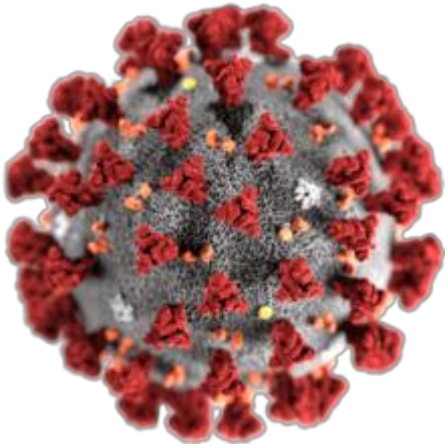
NUS National University of Singapore | Saw Swee Hock School of Public Health



COVID-19 Science Report: Diagnostics

NUS Saw Swee Hock School of Public Health
As of 08 May 2020

DOI: 10.25540/e3y2-aqye

Contents

Diagnostics 1
Current Diagnostics 1
Detection of Viral Genetic Material 1
Serological Testing 3
Antigen Testing 5
Imaging 5
Issues with Diagnosis Approaches 5
Use of Rapid Antibody Tests in Community 5
Specimen Sample Collection 6
Gene Target Choices 9
Imaging 9
Search Method 9
Acknowledgement 10
Appendix A 11
Table 1. Non-Commercial Laboratory Protocols 11
Table 2. Upcoming/Available Diagnostics 14
Table 3. Approaches for Coronavirus Diagnostics 52
Table 4. Gene Targets and Specimen Sample Types Tested with PCR 54
References 59

Diagnostics

For regular readers of this report, the latest additions have been highlighted in orange.

Some references were from preprints which are preliminary and yet to be peer reviewed, the results should be interpreted with caution.

Laboratory diagnosis plays an important role in disease and outbreak management. Fast and accurate laboratory diagnosis of a specific viral infection of interest contributes to prompt public health surveillance, prevention, and control measures. With wide accessibility and availability of an accurate laboratory diagnosis for early detection, local transmission and clusters can be prevented or at least delayed by isolating the laboratory-confirmed cases in a healthcare facility, and to have their close contacts quarantined and monitored at home. Furthermore, this facilitates the implementation of specific public health intervention such as the closure of specific high-risk facilities and areas associated with the laboratory-confirmed cases for prompt infection control and environmental decontamination.[1,2]

Current Diagnostics

Appendix A contains four summary tables:

1. Table 1 is a list of the latest non-commercial laboratory diagnostic protocols listed on WHO's COVID-19 webpage.
2. Table 2 is a list of available or upcoming commercial and non-commercial diagnostics. Diagnostics that can be used for point-of-care testing have been noted in Table 2 in the first column. FIND has a similar list compiled from publicly available information and from self-submissions by suppliers at https://www.finddx.org/covid-19/pipeline/.[3] Other lists include those compiled by Nature[4,5] and 360Dx/GenomeWeb.[6]
3. Table 3 is a list of approaches for laboratory diagnostics of coronaviruses by Zhang et al (2020).[7]
4. Table 4 is a list of the gene targets and specimen sample types tested with polymerase chain reaction (PCR) as reported in publications on clinical cases of COVID-19 published before 7 March 2020.

Detection of Viral Genetic Material

Chinese health authorities have posted the full genome of SARS-CoV-2 in GenBank and GISAID portal.[1] Several lab assays have been developed to detect SARS-CoV-2, as highlighted in WHO's guidance to COVID-19 laboratory testing of suspected cases. WHO first published five protocols for diagnostics using reverse transcriptase polymerase chain reaction (RT-PCR) on their COVID-19 webpage. These included protocols from Charité Institute of Virology in Germany and The University of Hong Kong (HKU), as well as those from Thailand, Japan, and China. A sixth protocol from US Centers for Disease Control and Prevention (CDC) was subsequently added on WHO's webpage on 29 January 2020.[8] The WHO webpage has since been updated with a different URL and with additional guidance documents.[9] A seventh protocol from Institut Pasteur in Paris, France, was added on WHO's webpage in March 2020.[10]

It should be noted that the protocols for diagnostics using RT-PCR published on WHO's webpage is for guidance and not an exhaustive list. Various institutions and governments

have chosen to develop their own protocols that might not be publicly available or published by WHO on their webpage.

As outlined in the sixth national treatment and diagnostic plan issued by China's National Health Commission, the diagnosis of COVID-19 still requires the detection of the genetic material of SARS-CoV-2 before classification as a confirmed case.[11]

The first validated diagnostic test was designed by Prof Christian Drosten's group from Charité Institute of Virology in Berlin, Germany.[1,12] The initial RT-PCR assay design was based on the SARS-CoV or SARS-related coronavirus, but with the release of the sequence, assays were selected based on the match against the SARS-CoV-2 virus. Two assays were used for the RdRp gene and E gene where E gene assay acts as the first-line screening tool and RdRp gene assay as the confirmatory testing. All assays were highly sensitive and specific, and do not cross- react with other coronavirus and also human clinical samples that contain respiratory viruses.

HKU uses two monoplex assays reactive with coronavirus under the subgenus Sarbecovirus which consist of SARS-CoV-2, SARS-CoV, and SARS-like coronavirus.[13,14] Viral RNA extracted from SARS-CoV could be used as the positive control. The N gene RT-PCR could be used as a screening assay and Orf1b assay as a confirmatory test. However, this protocol has only been evaluated with a panel of controls and only positive control, SARS-CoV RNA. Synthetic oligonucleotide positive control or SARS-CoV-2 have yet to be tested. This protocol has since been published in Clinical Chemistry on 31 January 2020.[14]

US CDC has shared the protocol for rRT-PCR assay with the primers and probes designed for the universal detection of SARS-like coronavirus and the specific detection of SARS-CoV-2.[15,16] However, the protocol has not been validated in other platform or chemistries apart from the protocol described, and the analyst has to be trained and familiar with the testing procedure and result interpretation. As of 4 February 2020, US CDC has obtained emergency use assessment (EUA) from the US Food and Drug Administration (FDA).[17] This allowed US CDC to ship their diagnostic test kits to laboratories that are designated by CDC as qualified or certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests in the US.

With the first batch of US CDC diagnosis kits shipped in February 2020, however, quality control issues were found with reagents pertaining to the third step N3 gene assay for universal detection of SARS-like coronaviruses.[18] As such, US CDC was reportedly producing new test kits, and that those with existing kits were provided with new guidelines to continue without the third step N3 gene assay.[19,20] An investigation had also been launched, with major concerns raised in the preliminary stages.[21,22] The US Food and Drug Administration (FDA) has since announced on 29 February 2020 a change in policy for certain laboratories to develop and begin using validated COVID-19 diagnostics (other than that by US CDC) before the FDA has completed the EUA review.[21,23] By the end of March, over 20 organisations (including US CDC and Wadsworth Center, New York State Department of Public Health) have obtained EUA approvals from US FDA for their diagnostics. IDT[24] and LGC, Biosearch Technologies[25] also have specific lots of their RT-PCR diagnostic kits approved for EUA by US FDA.

Cepheid's Xpert Xpress SARS-CoV-2 test is the first point-of-care diagnostics to obtain EUA approval from the US FDA.[26,27] Using samples obtained from nasopharyngeal swabs or nasal wash/aspirate, the test can produce results in 45 minutes. This point-of-care test can be run on Cepheid's automated GeneXpert Systems machines without having the samples sent to a laboratory. However, as each machine can only run one sample at a time, this

poses a limitation in true volume throughput of diagnostic tests run. Additionally, there are only an estimated 5000 machines in the US as of March 2020.

Mesa Biotech and Abbott Diagnostics also have point-of-care tests for SARS-CoV-2 genetic material that have obtained EUA approval from US FDA.[28,29] Mesa Biotech's Accula SARS-Cov-2 Test takes 30 minutes and runs on the Accula system machines.[30] Abbott Diagnostic's ID Now COVID-19 test takes only 5 to 13 minutes to run completely, and can run on Abbott's ID Now platform, which is reported to have about 18,000 existing machines around the world.[31]

Currently, most of the available diagnostics have focused on packaging the appropriate reagents and genetic primers and probes for using RT-PCR to amplify genetic material for detection of SARS-CoV-2. Additional methods include using microarray or microfluidic lab-on-chip technologies, CRISPR to isolate gene segments for diagnostics, and full genetic sequencing. The use of microarray or microfluidic technologies for miniaturised fast detection of genetic material in some instances could be considered to be rapid point-of-care testing, as samples could be run on miniaturised and/or automation machinery instead of a full laboratory. However, the caveat would be that the accompanying machinery and reagents are widely distributed and available across different sites and/or in the field.

Mammoth Biosciences was previously reported to be developing a CRISPR-based diagnostics for detection of SARS-CoV-2 in partnership with University of California San Francisco.[32-34] In a published *Nature Biotechnology* paper by Broughton et al (2020), the authors described the development and initial validation of the new assay that uses CRISPR Cas12 guide ribonucleic acids (gRNAs).[35] Swab samples first go through the usual RNA extraction, followed by reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) to amplify the SARS-CoV-2 RNA. Cas12 gRNAs then detect for the presence of the SARS-CoV-2 E gene and N2 region of the N gene, and proceed to cleave the FAM-biotin reporter molecules. A lateral flow assay test strip would then detect the uncleaved (first detection line – control line) and cleaved (second detection line – test line) reporter molecules. The complete assay time from start to finish takes only about 40 minutes.

Next generation sequencing (NGS), sometimes referred to as deep sequencing, refers to a sequencing approach that allows for reactions and analysis to occur simultaneously. Multiple sequencing reactions can occur in parallel without having physical separation in tubes, capillaries, or lanes for different reactions.[36] NGS-based tests can be less time consuming and provide higher throughput, and be less labour-intensive than traditional Sanger sequencing. The Fulgent Coronavirus Disease (COVID-19) Next Generation Sequencing (NGS) test is a NGS-based test to detect SARS-CoV-2. In addition to detecting the virus, this test also characterizes the entire viral genome, thereby going beyond just detection of a few gene targets as in RT-PCR tests. NGS tests, like the one by Fulgent Genetics, will not be limited by a shortage of reagents, which has proven to be a roadblock for large scale processing of RT-PCR based tests in the market currently.[37]

Serological Testing

Serological tests can be used to assess both active and historical infection within the community. For diagnosis of acute infections, there is a lag period from start of infection to a true positive diagnosis due to a delay in the immune response of antibodies specifically targeting the SARS-CoV-2 virus. The presence of IgM antibodies for SARS-CoV-2 has been observed in a cohort study to take 10 days or later after the onset of symptoms,[38] but has been separately observed to take as early as 7 days in a patient.[38] However, serological

tests using immunoassay test strips can also provide rapid point-of-care qualitative detection of antibodies for better screening before further confirmatory tests.

Singapore has developed an approach of using serological testing to diagnose cases that earlier had COVID-19.[39,40] This test for the antibodies for SARS-CoV-2 was developed by Prof Wang Linfa's group in Duke-NUS Medical School.

Rapid point-of-care antibody tests have been developed by Guangzhou Medical University under the guidance of famed researcher Dr Zhong Nanshan and are already in use in China.[11,41] Guangzhou Wondfo Biotech and Innovita Biological Technology have already received EUA approvals from the China National Medical Products Administration (NMPA) for their antibody test kits.[42-45] Guangzhou Wondfo Biotech has also obtained CE Mark for their Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) that tests for both IgM and IgG antibodies.[46,47] Pharmact AG from Germany,[48] Zhejiang Orient Gene Biotech,[49,50] and SD Biosensor[51] all have commercially available immunoassay test strips for qualitative detection of antibodies that can be used for point-of-care testing. Other rapid test kit development and commercialisation efforts by Jiangsu Medomics Medical Technologies,[52] Shenzhen Tisenc Medical Devices,[53] and Nankai University[54] are also underway. These test strips are all expected to take about 15 to 20 minutes, a major time reduction compared to using RT-PCR.

Jiangsu Medomics Medical Technologies (China-based sister company of BioMedomics, USA) have created a point-of-care lateral flow immunoassay that simultaneously detects both IgM and IgG antibodies against SARS-CoV-2, named COVID-19 IgM/IgG Rapid Test.[52] In a published *Journal of Medical Virology* paper by Li et al (2020), the team found a sensitivity of 88.66% and specificity of 90.63% through testing samples from 397 positive case patients and 128 negative control patients.[55] The use of whole blood (diluted with buffer to improve flow) can be used and can produce results within 15 minutes. Comparison of fingerstick whole blood with both plasma and serum from venous blood found no differences in results for 7 positive case patients and 3 negative control patients. By using both IgM and IgG, the test can be used for detection of patients at different infection stages. Over 500,000 of the COVID-19 IgM/IgG Rapid Test was reported to have been sold in China, and are currently being sold in Italy having received CE Mark for in vitro diagnostics (IVD) on 8 March 2020.[56] BioMedomics is seeking to obtain EUA approval from US FDA.[57,58]

Cellex is the first company supplying a rapid point-of-care lateral flow immunoassay test to obtain EUA approval from US FDA. However, in the instructions for use (IFU) provided on FDA's website, the test cartridge was specified to only be used to "aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests."[59] The test can be used with serum, plasmas, or whole blood from venepuncture, but not blood from fingerstick.

In March 2020, FIND launched an evaluation of SARS-CoV-2 immunoassays using a standardized independent protocol.[60] Although the initial round of submissions allowed for manual ELISA and machine-based or lateral flow rapid tests, the first selection announced prioritised evaluation of only rapid diagnostic tests (RDTs). The final list of this first selection covered 27 RDTs for detection of antibodies targeting SARS-CoV-2. Five RDTs for detection of SARS-CoV-2 antigen will also be tested. Results are not available as of 9 April 2020.

Carbohydrate based glycation pattern detection diagnostic has been developed by Iceni Diagnostics.[61] They are using lateral flow assays (also known as also known as lateral flow immunochromatographic assays) as a point-of-care test. Lateral flow assays are advantageous because without the need for specialized and costly equipment, you can produce a result quickly (15 minutes) and is relatively inexpensive and simple to use. [62] Being

based on glycan molecules, the virus is unable to mutate and avoid surveillance because even though the genetic sequence of the virus can mutate, the glycans it uses does not change. [63]

Antigen Testing

The test of antigens specific to the SARS-CoV-2, such as the nucleocapsid (N) protein and the S1 or S2 domains of the spike (S) protein, can be done using monoclonal antibodies (mAbs).[5] Such tests would still require respiratory tract specimen samples (eg by nasopharyngeal or oropharyngeal swabs) for detection testing. Commercialisation efforts of antigen testing into rapid point-of-care lateral flow assay cartridges, as well as the validation testing of these commercialised rapid tests, are underway.[5,64] Unlike diagnostics using PCR, which is a process that amplifies the viral RNA, antigen testing using a lateral flow assay with direct swab samples does not have such an amplification process. Such tests thus run a higher risk of not being able to detect viral material from a swab, and producing false negative diagnosis. There have been reports of such lateral flow assay cartridges for antigen testing already in the market, but that have low accuracy and have not been approved for use.[65]

Imaging

In the sixth national treatment and diagnostic plan issued by China's National Health Commission, cases diagnosed using chest CT Scans were not continued as part of the count of new confirmed cases.[11] China had previously announced that they would include in the count of COVID-19 cases, those that were diagnosed using chest CT Scans.[66] This was due to the limited diagnostic kits and resources for testing of SARS-CoV-2 genetic material. This proposed method of early diagnosis has been explored and published in the Radiology journal.[67,68] Some studies have indicated, albeit with small samples, that CT scans could show indications of COVID-19 before onset of symptoms or positive RT-PCR test.[69-71] Alibaba has also developed an artificial intelligence (AI) model using data from 5000 confirmed cases that has 96% accuracy rate in detecting differences in chest CT scans to distinguish patients with COVID-19 vs ordinary viral pneumonia.[72]

Issues with Diagnosis Approaches

Use of Rapid Antibody Tests in Community

The use of rapid point-of-care serological tests for diagnosis of SARS-CoV-2 infection has been a concern for global regulators.[73,74] Immunoassay tests for antibodies against SARS-CoV-2 run the risk of false negatives, particularly in the early stages of infection, since there is usually a delay before antibodies are detectable, with different individuals mounting different immune responses.[74] There is also a risk of false positives if individuals have formed similar antibodies with exposure to other types of coronaviruses.

Rapid point-of-care immunoassay test strips using just blood from fingerstick is convenient, minimises exposure to healthcare workers, and could serve as first-level screening in community before confirmatory testing of viral genetic material. When used for patients already showing symptoms and/or when physicians are suspicious of infection, such tests could save time and maximise limited resources. Adding these tests, instead of full replacement of the PCR tests of genetic material, could be beneficial considering the major global shortage of supplies of key reagents for RNA extraction needed for the PCR test.[75]

Public Health England (PHE) has previously warned against the use of rapid point-of-care serological tests at home or in community pharmacies due to the lack of information on

accuracy and published evidence.[76] However, Prof Sharon Peacock from PHE announced on 25 March 2020 that 3.5 million of such rapid serological tests have been ordered and will be rolled out for use after evaluation.[77] The UK government's chief medical adviser, Prof Chris Whitty, has put in question when the tests would be available. The priority of such tests would likely be for healthcare workers, such that those shown to have immunity are allowed to return to work.

The Australian government has also announced that 500,000 of such rapid point-of-care tests have been ordered to be used in hospitals and clinics for screening purposes.[78] As of 26 March 2020, Australia has five such tests with approval for inclusion in the Australian Register of Therapeutic Goods (ARTG) from the Department of Health Therapeutic Goods Administration (TGA).[79]

Specimen Sample Collection

The sites of biological sampling can affect the sensitivity of diagnostic tests relying on detection of genetic material. A previous study by Kim et al (2011) has found that detection strengths of using nasopharyngeal (nasal) or oropharyngeal (throat) swabs differ for different pathogens infecting the respiratory tract, and that not one is superior than the other for all cases.[80]

For SARS-CoV and MERS-CoV, specimens collected from the lower respiratory tract such as sputum and tracheal aspirate have higher and more prolonged levels of viral RNA. MERS-CoV viral load is also higher for severe cases and has longer viral shedding as compared to the mild case. Although upper respiratory tract specimens such as nasal or throat swabs could be used, it has a lower viral load and could result in false-negative tests among the mild cases.[81,82] This is one key characteristic that may be similar to SARS-CoV-2.

Current recommendation by US CDC requires the use of BOTH nasal and throat swabs to obtain specimen from upper respiratory tract of potential case with COVID-19 for diagnostic testing using RT-PCR.[83] However, initial rapid guidelines from China only indicated the use of throat swabs.[84]

Latest published findings from Yang et al (2020) specific for COVID-19 have found that testing of specimens obtained from nasal swabs, as well as from sputum, are more effective than throat swabs, for the detection of SARS-CoV-2.[85] The authors warned that “throat swabs were not recommended for the viruses detection, especially the samples collected 8~14 and ≥15 days after onset of illness (d.a.o.) from mild cases, which may result in a large proportion of false negative results.” The authors concluded that “sputum is most accurate for laboratory diagnosis of (COVID-19), followed by nasal swabs, while throat swabs was [sic] not recommended for the diagnosis.” However, the authors recognised the limitation that preliminary investigations found that only about a quarter of COVID-19 patients showed had production.

Interestingly, the authors found that for severe cases, bronchoalveolar lavage fluid (BALF) had 100% positive detection rate while specimens from upper respiratory tract (sputum, nose swab, and throat swab) did not have as strong detection rates.[85] This might be a case whereby the severe cases reflect the deep infection of the lower respiratory tract, causing the pneumonia-like symptoms. The use of only nasal or throat swabs to get at an official diagnosis could thus prove to be frustrating, particularly when specimens from the upper respiratory tract might show a negative result even though all clinical signs indicate otherwise. This could cause delayed diagnosis, containment actions, and treatment regimes, and as such, the recommendation of CT scans as an added layer. On the contrary, the small sample of three patients that were mild cases with BALF tested had 0% positive detection. It

could be these cases are mild because the SARS-CoV-2 did not infect the lower respiratory tract but remained in the upper respiratory tract, which allowed for better detection if using samples from sputum or nasal swabs.

A limitation of the Yang et al (2020) study was that it was conducted with COVID-19 patients that have already been admitted to the hospital and started on antiviral treatments.[85] Their findings might thus be limited in being fully applicable to the scenario of diagnosis of potential cases. However, the study does also raise questions on the risk of false negatives leading to early discharges out of isolation and quarantine of existing diagnosed cases.

To note, nasal and throat swabs:

- could cause discomfort and even bleeding
- would require experienced healthcare provider to administer
- could risk exposure to healthcare provider
- does not obtain specimens from lower respiratory tract

A study by To et al (2020) have found that SARS-CoV-2 was detected in saliva samples from 11 out of 12 COVID-19 patients.[86] This suggests that saliva samples could be a potential alternative or additional specimen for diagnostic testing, especially in scenarios with limited trained healthcare providers outside of the hospital setting, and with aim to reduce exposure risk during specimen collection. A preprint study by Tu et al (2020) has found that when compared to healthcare worker-collected nasopharyngeal swabs, self-collected tongue, nasal, and mid-turbinate samples have high sensitivities 90% and above.[87] A preprint study by Kojima et al (2020) has also found that supervised self-collection of oral fluids and nasal swabs, but not unsupervised self-collection of oral fluids, could perform just as well as, if not better than clinician-collected nasopharyngeal swab samples.[88]

As of 9 March 2020, Hong Kong has launched an initiative to have private general practitioners (GPs) and family doctors help collect deep throat saliva samples from potential cases with COVID-19.[89] The initiative to collect saliva samples is in light of the lack of protective gear by private doctors to collect nasal swabs. This initiative aims to improve community surveillance through expanding testing sample collection beyond that currently done at 17 public hospitals and 64 government-run outpatient clinics.

Singapore's Lucence has also recently launched a viral sample collection kit, the SAFER-Sample (Stabilization of nucleic Acid Formulation for Evaluation of RNA) kit.[90] The kit contains a bottle with stabilization fluid that keeps the viral RNA stable at room temperature for up to a week after mixing with the sample at the point of collection. Non-invasive sample types such as saliva could also be collected with the SAFER-Sample kit. This kit could potentially increase facilitation of initiatives to expand specimen sample collection capabilities, particularly since it does not require immediate refrigeration, a barrier private GPs and family doctors have highlighted as they have limited refrigerator space, with most dedicated to storing medications and vaccines.[89]

Rutgers University's RUCDR Infinite Biologics has obtained first EUA approval from the US FDA to use saliva samples as the main specimen in tests for SARS-CoV-2.[91,92] Unlike swab samples, saliva samples can be collected without requiring close interaction of healthcare provider (self-collection) with the person under investigation. The EUA summary specifies that collection of saliva samples should be done in a healthcare setting under the supervision of a trained healthcare provider, using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device.[92] Testing is also limited to Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologics. The test is a modified version of the previously

authorized Thermo Fisher Applied Biosystems TaqPath COVID-19 Combo Kit. Parallel testing of nasopharyngeal and oropharyngeal swab samples with saliva samples using this test found 100% agreement for positive and negative results.

As of 16 April, US FDA announced a further expansion of current COVID-19 testing capabilities through the possibility of using spun synthetic swabs, which have a similar design to Q tips, for self-collection of samples at the front of the nose by patients.[93] This would allow improved comfort for the patients, while minimizing exposure of healthcare providers.

Process of Laboratory Diagnosis

A commentary [94] published in the Journal of Clinical Microbiology on 3 April 2020 highlights the current issues and challenges surround the process of laboratory diagnosis. This can be roughly divided into pre-analytical, analytical, and post analytical issues.

Pre-Analytical Issues:

Other than the aforementioned issues with specimen sample collection, there are also theoretical risks of transmission. The possible airborne transmission of SARS-CoV-2 poses risks of transmission during Nasopharyngeal/Oropharyngeal swab collection. Proper PPE must be given to healthcare workers doing these swabs. If proper PPE cannot be administered to those collecting samples, other means of collecting samples must be considered. As mentioned before, possible alternatives include self-collected saliva specimens and nasal washes. However, some saliva/NPS/OPS miss early infection and as such multiple tests may need be done, or samples must be collected from the lower respiratory tract (eg. Bronchoalveolar lavage).

Analytical Issues

Assay selection. Based on previous usage for detection of influenza viruses, rapid antigen lateral flow assays are expected to suffer from poor sensitivity, despite having a fast turnover time and reduced costs. Another concern is the viral load variability in patients, causing the antigen assays to give false negative results. Furthermore, serology methods, like detecting IgG and IgM are best used retrospectively. IgM is thought to be nonspecific and specific IgG takes weeks to develop and as such, is not useful in active case management, apart from diagnosing COVID-19 late in patients.

Assay selection for molecular detection. Advanced techniques such as next generation sequencing and metagenomic next generation sequencing, while currently impractical for diagnosing COVID-19, may still be needed as it can help predict future mutations in the viral genome.

Target selection for real time RT-PCR assays. In such real time RT-PCR assays, at least two molecular targets, ideally one conserved region and one specific region, must be included. This is to mitigate the effect of cross reaction with other coronaviruses as well as the effects of genetic drift, which is expected to increase as the virus expands in new populations.

Post-Analytical

Interpretation of molecular results. Despite possible correlations, COVID-19 disease severity or response to therapy should not be based on viral loads determined by rRT-PCR but they can be used as an indicator of transmissibility in patients.

Test of cure and test of infectivity. Discharge criteria is a critical issue, and it primarily deals with whether hospitals test for complete cure, or test of whether the patients are still infective. Discharged patients are still likely to infect others if they are still shedding the virus, yet may

have no remaining symptoms. NP swabs or OP swabs may not be sufficient in determining the test of cure or test of infectivity. The gold standard so far has been two consecutive negative rRT-PCR tests from rectal swabs. However, patients with positive rectal swabs would still be shedding the virus and are still infectious.

Gene Target Choices

In addition to different types of specimen samples being collected by different healthcare teams across institutions and nations, the gene targets of choice and PCR protocols used also differs. Table 4 in Appendix A presents a summary of the gene targets and specimen sample types tested with PCR as reported in selected publications on clinical cases of COVID-19 published before 7 March 2020.

It is important to note that virus mutation might affect sensitivity of test kits. In particular, tests which only target a single target, or that target easily mutated areas of the virus genome are theoretically likely to have lower sensitivity.

Imaging

A recent Lancet study has indicated that CT findings in patients with COVID-19, such as that of ground glass opacities and consolidations, are not specific for COVID-19.[95] Hence, the authors assert that this limitation confers a low positive predictive value to the use of CT in diagnosis, unless disease prevalence is high, and therefore does not believe that the CT adds diagnostic value. Regardless of negative results on a CT, it should still be confirmed with RT-PCR tests, and the patient should still be isolated. The results of the CT scan hence would not influence management in this case. Furthermore, the usage of CT scans during the pandemic raises additional logistical challenges and machines can become vectors of infection, even with proper cleaning protocols.

Search Method

Searches have been conducted for the latest information related to diagnostics for COVID-19 (previously 2019-Novel Coronavirus or 2019-nCoV) since 28 January 2020. Searches were done on PubMed and Google Search using key words that included: coronavirus; Wuhan; diagnostic; diagnostics; diagnosis; diagnoses; novel coronavirus; 2019 novel coronavirus; 2019-nCoV; COVID-19; SARS-CoV-2. Google Search results reviewed included webpages of: government and international bodies with official information and guidelines (WHO, Europe CDC, US CDC, US FDA), diagnostic protocols, scientific commentaries, market news, and press releases. All relevant links in the webpages were reviewed and relevant information used and referenced. A latest list of potential commercial kits in the works was also provided on 29 January 2020 by Dr Kim J Png through personal communications. This list was compiled by Dr Png from web searches and review of latest business news. The list served to verify and supplement our team's own search above for review. Subsequently, a list of biomedical news sites (Bioworld, Genetic Engineering & Biotechnology News, GenomeWeb/360Dx, Verdict Medical Devices) were also reviewed regularly as "go-to" sites to provide latest updates on commercial diagnostics developments. These in turn seed new searches to obtain official press releases, commercial listings, and news reporting. To note, the latest information of diagnostics being used and developed in China remain scarce or difficult to review (in Chinese, not indexed in non-Chinese search engines, or not reported in non-Chinese media news outlets). Therefore, China news sources in English language (CGTN, ChinaDaily, Global Times) were used.

Acknowledgement

We are grateful to the following for their assistance on the review of articles and input into the report:

Dr Shweta R Singh

Wen Wen Chen

Priya Balavela

Arvindh Ulagapan

Appendix A

Table 1. Non-Commercial Laboratory Protocols

Molecular tests (rRT-PCR)								
Type	**Organisation**	**Date**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,96]	13 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay Additional confirmatory assay: N gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. Additional confirmatory assay **Technical LOD:** 8.3 RNA copies/reaction, at 95% hit rate; **95% CI:** 6.1-16.3 RNA copies/reaction.	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,12]	17 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. (Preliminary experiment compared single probe assay for SARS-CoV with single probe assay for SARS-CoV-2.)	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control. • Synthetic control RNA for SARS-CoV-2 E gene assay is available via EVAg. • Synthetic control for SARS-CoV-2 RdRp is expected to be available via EVAg from Jan 21st onward.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**School of Public Health, The University**	16 Jan 2020	**Primer and Probe**	Positive control using SARS-CoV RNA Wide dynamic range of 2^{-4} to 2000	Exclusivity Negative results against all of these preparations:	Available • Positive control (Available from HKU)	28 min 40 sec of cycle	(no info)

Molecular tests (rRT-PCR)								
Type	**Organisation**	**Date**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	of Hong Kong (HKU)[13,14]		Assay 1 (Target: ORF1b-nsp14 gene) Assay 2 (Target: N gene)	$TCID_{50}$/reaction.	• RNA extracted from cultured viruses • RNA from retrospective human clinical specimens previously tested positive for other infections • RNA from control human clinical specimens	Primers and probes: • HKU-ORF1b-nsp14F • HKU- ORF1b-nsp14R • HKU-ORF1b-nsp141P • HKU-NF • HKU-NR • HKU-NP	time for each assay	
rRT-PCR	**Chinese Center for Disease Control and Prevention**, Beijing, China[97]	21 Jan 2020	**Primer and Probe** Target 1 (ORF1ab gene) Target 2 (N gene)	(no info)	(no info)	Available	(no info)	(no info)
RT-PCR	**Department of Medical Sciences, Ministry of Public Health**, Thailand[98]	Jan 2020	**With gel electrophoresis**	(no info)	(no info)	Available Primers: • NbatCoV_F1 • NbatCoV_R1	107 min of cycle time	(no info)
RT-PCR	**National Institute of Infectious Diseases**, Japan[99]	23 Jan 2020	**With gel electrophoresis** (Nested RT-PCR) **Primer and Probe** (Real-time RT-PCR)	(no info)	(no info)	Available Primers and probes: • NIID_2019-nCOV_N_F2 • NIID_2019-nCOV_N_R2 • NIID_2019-nCOV_N_P2	81 min for Nested RT-PCR 95 min for Real-time RT-PCR	(no info)
rRT-PCR	**Centers for Disease Control and Prevention**, Atlanta, USA[15,16]	24 Jan 2020	**Primer and Probe** 3 N gene targets 1 human RNase P gene control	(no info)	(no info)	Available Primers and probes: • 2019-nCOV_N1_F • 2019-nCOV_N1_R • 2019-nCOV_N1_P • 2019-nCOV_N2_F • 2019-nCOV_N2_R • 2019-nCOV_N2_P • 2019-nCOV_N3_F • 2019-nCOV_N3_R • 2019-nCOV_N3_P • RP_F • RP_R • RP_P	43 min 45 sec of cycle time for each assay	(no info)

Molecular tests (rRT-PCR)								
Type	**Organisation**	**Date**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
rRT-PCR	**Institut Pasteur**, Paris, France[10]	2 Mar 2020	**Primer and Probe** 2 RdRp gene targets with Charité's E gene target as confirmatory	100 or more copies of RNA genome equivalent per reaction always detected. Samples containing 10 copies of RNA genome could be detected with multiplex assay.	Cross-reactivity with other respiratory viruses was tested and were all negative in reactivity with the two RdRp gene targets.	Available Primers and probes: • nCoV_IP2-12669Fw • nCoV_IP2-12759Rv • nCoV_IP2-12696bProbe(+) • nCoV_IP4-14059Fw • nCoV_IP4-14146Rv • nCoV_IP4-14084Probe(+) • E_Sarbeco_F1 • E_Sarbeco_R2 • E_Sarbeco_P1	61 min of cycle time for each assay	(no info)

RT-PCR: reverse transcription polymerase chain reaction

rRT-PCR: real-time reverse transcription polymerase chain reaction

LOD: limit of detection

ORF: open reading frame

E gene: envelope gene

RdRp: RNA-dependent RNA polymerase

N gene: nucleocapsid protein gene

RNase P gene: Ribonuclease P gene

Table 2.1 Upcoming/Available Diagnostics: Molecular tests

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
RT-PCR	Bioperfectus Technologies[100] China	14 Jan 2020	**RT-PCR test kit**	(no info)	(no info)	Available as scientific research product – does not require registration[100]	(no info)	(no info)
Genome sequencing	Oxford Nanopore[101,102] UK	22 Jan 2020	Works with public health labs globally to support rapid sequencing of SARS-CoV-2 through sharing of methods / workflows. Nanopore sequencing workflows can provide a consensus viral genome from sample within a day.	(no info)	(no info)	Available. 28 January: US Centers for Disease Control and Prevention (CDC) releases nCoV genomes sequenced with nanopore sequencing 29 January: A paper in the Lancet characterised full-length genomes of 2019-nCoV patients using Nanopore sequencing, providing important information on possible virus origins and cell-binding receptors that is crucial for determining viral transmission capacity. 30 March: Singapore sequences its genome in less than 7 hours 14 April: In the UK, more than 600 genomes have been uploaded onto GISAID, using nanopore sequencing[103].	(no info)	(no info)
End-to-end solution of sample processing to	Oxford Nanopore[101,104] UK	22 Jan 2020	**ARTIC project** A 'lab-in-a-suitcase' solution for processing samples from	Not stated but described to have high sensitivity compared to	(no info)	Available 3 February: First Belgian nCoV sample	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
epidemiological info generation			viral outbreaks, to generating real-time epidemiological information interpretable and actionable by public health bodies. Deployable to remote/resource-limited locations. Based on viral genome data generated prospectively during similar outbreaks (eg. MERS, SARS etc). Relies on direct amplification of the virus using tiled, multiplexed primers.	metagenomic approaches.[105]		arrives in a lab at 5pm and using the ARTIC protocol, the sequence is completed by 9am. 3 March: The SARS-CoV2 virus from Scotland's first case is sequenced in under 24 hours using nanopore sequencing and the ARTIC protocol[103].		
RT-PCR	Co-Diagnostics[106-108] USA	23 Jan 2020	**Logix Smart Coronavirus COVID-19 test** RT-PCR kit with lower false positive	100% (21/21)[109]	No specific statistics but claims to have ability to reliably and accurately differentiate between similar genetic sequences, in order to reduce the likelihood of a false-positive diagnosis. Company shared that it achieves this by creating reactions that are far more specific than competing PCR technologies and 2.5 million times more effective in reducing amplification errors.[106,110] 100%[109]	Commercially available for sale on 10 Feb 2020.[107] Received CE Mark 24 Feb 2020.[111] Obtained EUA approval from US FDA 3 Apr 2020.[108]	Within 2 hours[109]	(no info)
RT-PCR	Altona Diagnostics[112] Germany	23 Jan 2020	**Realstar SARS-CoV-2** RT-PCR kit	Stated to be high, with no accompanying statistics. The kit did not show any unspecific E gene signals[113].	No cross reactivity with 21 human pathogens[113]	Available FDA EUA issued on 22/4/2020	2:15 hours[113]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
Real Time RT-PCR	BGI[114-116] (Pathomics Health as distributor) China	23 Jan 2020	**Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV** In vitro RT-PCR combining fluorescent probing.[117] Real-time RT-PCR assay for qualitative detection of SARS-CoV-2 in throat swabs and bronchoalveolar lavage fluid (BALF).	BALF: 81% Throat Swab: 91.2% RNA: 97.1% Combined: 88.1%[118]	BALF: 100% Throat Swab: 100% RNA: 96.2% Combined: 99.6%[118]	Commercially available. Received CE Mark for IVD 2 Mar 2020.[119] BGI is also engaged with relevant organizations in Hong Kong, Taiwan, Brunei, Thailand, Nigeria, South Africa, to supply the test kits.[114] Passed emergency approval procedure of China's NMPA. Obtained EUA approval from US FDA 27 Mar 2020.[115,116] Approved for inclusion on Australia's ARTG on 10 April 2020.	3 hr	(no info)
Combination of RT-PCR and meta-genomics detection	BGI[114] (Pathomics Health as distributor)[120] China	23 Jan 2020	**2019-nCoV PMseq Kit** A metagenomics sequencing kit based on combinatorial Probe Anchor Sythesis. Faster SARS-CoV-2 virus detection, and able to detect both known and novel microorganisms, enabling monitoring of evolution during transmission.	(no info)	(no info)	Has been providing technical support for the scientific clinical prevention and control of the epidemic in Wuhan. Passed emergency approval procedure of China's NMPA.	SARS-CoV-2 detection stated to be faster than Fluorescent RT-PCR kit. For detection of unknown pathogens, Within 5 hours, 128 samples can be simultaneously screened and sequenced by SE50, and 128 samples can be simultaneously tested and sequenced by PE100 in 22 hours, as well as	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
							possible mutation and evolution monitoring	
Microfluidic	Veredus Laboratories[121-123] Singapore	24 Jan 2020	**VereCoV** Lab-on-Chip platform integrating PCR and microarray Claims to detect MERS-CoV, SARS-CoV and SARS-CoV-2 in a single test	Stated to be high but with no accompanying statistics.[124]	Stated to be high but with no accompanying statistics.[124]	Available for RUO since Jan 2020. Provisional approval for IVD by Singapore's HSA since Mar 2020.[123] Used for testing of swab samples from Singapore's land, sea and air checkpoints since Mar 2020.[125]	2 hours[126]	(no info)
CRISPR-based diagnostics	Sherlock Biosciences[34,127-129] (Plus collaboration with Cepheid)[129] USA	24 Jan 2020	**SHERLOCK (Specific High-sensitivity Enzymatic Reporter unLOCKing)** SHERLOCK platform uses various CRISPR proteins (Cas13, Cas12a, and Csm6) to allow for simultaneous detection of multiple nucleic acids.[129]	(no info)	(no info)	Protocol published 14 Feb 2020.[130,131]	(no info)	(no info)
Real-time RT-PCR	ScienCell Research Laboratories[132-134] USA	24 Jan 2020	**ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit** Tests for two gene targets: N1 & N2	100% (30/30) 30 nasopharyngeal swabs spiked with SARS-CoV-2 RNA (not actual clinical sample) serving as contrived positive samples.[133]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[133]	Commercially available. Obtained EUA approval from US FDA 3 Apr 2020.	43 min 45 s cycle time for each gene	(by quote)
Microfluidic	Lexagene[135] USA	27 Jan 2020	Genetic analyser using microfluidic technology	(no info)	(no info)	Expected to be commercially available in Q3 2020.	1 hr	(no info)
Real-time RT-PCR	Liferiver Biotech[136,137] China	29 Jan 2020	**Fluorescent PCR**[137]	(no info)	(no info)	Commercially available.	(no info)	€ 991[138]
Real-time RT-PCR	Liferiver Biotech[136,139] China	29 Jan 2020	**Multiplex RT-PCR**[139]	(no info)	(no info)	Commercially available.	(no info)	€ 1347[140]
Real-time RT-PCR	GenScript[136,141,142]	29 Jan 2020	**qRT-PCR**	"This assay is RUO and has not been tested on	"This assay may have cross-reactivity with	Commercially available for RUO.	(no info)	(by quote)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	USA		Targets RdRp gene, N gene and E gene in Wuhan-Hu-1 genome (GenBank sequences NC_045512.2) [same as Charite's first protocol]	clinical samples. We make no claims on the performance of this assay." [141]	other coronavirus family members such as causative agents of the Middle East Respiratory Syndrome (MERS) or Severe Acute Respiratory Syndrome (SARS)."[141]			
NGS	IDbyDNA[143,144] USA	29 Jan 2020	Next-generation sequencing-based metagenomics, allows enhanced pathogen detection and profiling in comparison to conventional PCR testing.[144]	(no info)	(no info)	Commercially available.	(no info)	(by quote)
Real-time RT-RAA	Beijing Ditan Hospital[145] China	29 Jan 2020	**Real time Reverse-Transcription Recombinase Aided Amplification (RT-RAA) assay** Novel isothermal nucleic acid amplification technique for detection of SARS-CoV-2. Assay was performed at 42°C within 30min using a portable real-time fluorescence detector,	(Recombinant plasmids containing conserved ORF1ab genes was used to analyse the specificity and sensitivity.)	(Recombinant plasmids containing conserved ORF1ab genes was used to analyse the specificity and sensitivity.)	Clinical trials phase.	(no info)	(no info)
CRISPR-based diagnostics	Mammoth Biosciences[32-35] (Partnering with UCSF Researchers) USA	30 Jan 2020	**SARS-CoV-2 DNA Endonuclease-Targeted CRISPR Trans Reporter (DETECTR)** Using the CRISPR Cas12 that cleaves a FAM-Biotin reporter molecule. Tests for two gene targets: E & N2.	95% (Using contrived reference samples and clinical samples from US patients, including 36 patients with COVID-19 infection and 42 patients with other viral respiratory infections) (Press release:[146] Study:[35]	Specificity: 100% (Using contrived reference samples and clinical samples from US patients, including 36 patients with COVID-19 infection and 42 patients with other viral respiratory infections) (Press release:[146] Study:[35]	Developed. Awaiting EUA from US FDA (pending clinical validation) (Press release:[146] Study:[35]	45 minutes (with manual RNA extraction) (Press release:[146] Study:[35]	(no info)
Real-time RT-PCR	CerTest Biotec[147]	30 Jan 2020	**VIASURE 2019-nCoV Real Time PCR Kit**	97.5%[149]	>99.9%[149]	Available.	120 minutes[149]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	Spain		Amplification of a fragment of the S gene.[148]			Received CE Mark for IVD for the version adapted for the BD MAX™ System.[148] Approved for inclusion on Australia's ARTG on 21 March 2020.		
PCR-based genotyping	Genomica[150,151] Spain	30 Jan 2020	**CLART COVID-19** Based on Genomica's CLART technology of PCR-based genotyping with low-density microarray.	>96%[152]	98%	Available. Received CE Mark 6 Mar 2020.[153]	< 5 hr	(no info)
qPCR	Primerdesign[154-159] (molecular diagnostics division of Novacyt) France/UK	31 Jan 2020	**Genesig Real-Time PCR COVID-19 (CE)** *[Previously Coronavirus (Strain 2019-nCoV) Easy/Standard Kit]*[155] Can run on multiple molecular testing platforms, including Primerdesign's own genesig® q16 and q32 instrument	96%[160]	100%	Commercially available. Received CE Mark for IVD 17 Feb 2020.[161,162] Obtained EUA approval from US FDA 20 Mar 2020.[158]	< 2 hr 64 min 30 s cycle time per gene[159]	(by quote)
RT-PCR	Roche[163-166] Switzerland	31 Jan 2020	**Cobas SARS-CoV-2 Test** Runs on the Cobas 6800/8800 systems. Tests for two gene targets: ORF1ab & E.	100% (50/50) 50 nasopharyngeal swab clinical samples spiked with cultured SARS-CoV-2 virus Low (1.5x LoD) and moderate (4x LoD) contrived positive samples [166]	100% (100/100) 100 nasopharyngeal swab clinical samples serve as negative controls.[166]	Commercially available. Obtained EUA approval from US FDA 13 Mar 2020.[165] CE Mark for IVD. Approved for inclusion on the Australia's ARTG on 20 March 2020. Date of HSA Provisional Authorisation: 19/03/2020[167]	3 hr 30 min	(no info)
RT-PCR	A*STAR[4,168] (Manufactured by Singapore's MiRxes which has	1 Feb 2020	**A*STAR Fortitude 2.0** Supports 188 tests per kit	100%[170]	100%	Available but not for commercial sale yet.	90 minutes	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	a nonexclusive license)[169] Singapore					Provisional authorization for clinical use from Singapore's HSA.[4,169]		
Real-time RT-PCR	GeneFirst[171] UK	3 Feb 2020	Capable of detecting only the SARS-CoV-2	(no info)	(no info)	Available	< 3 hr	(no info)
Real-time RT-PCR	GeneFirst[171] UK	3 Feb 2020	Multiplex assay which simultaneously detects SARS-CoV-2 as well as 17 other common viruses and bacteria	(no info)	(no info)	Available.	< 3 hr	(no info)
(no info)	TCM Biosciences[172] South Korea	3 Feb 2020	**TCM-Q Corona Ⅲ**	(no info)	(no info)	Developed as of 3 Feb 2020. Submitted to Korean CDC for EUA.	(no info)	(no info)
Real-time RT-PCR	Kogene Biotech[172,173] South Korea	3 Feb 2020	**Powerchek 2019-nCoV Real-time PCR kit** Tests for two gene targets: E and RdRp.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 4 Feb 2020.[173,174] Approved for inclusion on the Australian Register of Therapeutic Goods.	(no info)	(no info)
RT-PCR	PCL[172] South Korea	3 Feb 2020	**Multiplex diagnostic kit** PCLMD-nCoV one step RT-PCR kit Organisation: PCL[175] Qualitative detection of SARS-Co-V-2 by sputum samples	Sensitivity: 100% (35/35) [175]	(no info)	Developed as of 3 Feb 2020. CE approved [175]	1 hr 45 min	(no info)
(no info)	Bioneer[172] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Assumed developed as of 3 Feb 2020. Submitted to Korean CDC for EUA.	(no info)	(no info)
(no info)	Lab Geneomics[172] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Undergoing commercialisation as of 6 Feb 2020	(no info)	(no info)
(no info)	CEVI[172]	3 Feb 2020	(no info)	(no info)	(no info)	In development as of 6 Feb 2020	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	(Partnership with Wells Bio) South Korea							
Enzyme-assisted nanocomplex	iHealthtech[122,176] (Asst Prof Shao Huilin) Singapore	3 Feb 2020	**enVision (enzyme-assisted nanocomplexes for visual identification of nucleic acids)** Uses enzyme-assisted nanocomplexes	(no info)	(no info)	In development.	30 min	(no info)
RT-PCR	Biomeme[177,178] USA	4 Feb 2020	Shelf-stable strip with 3 reaction wells, each reaction contains lyophilized master mix, multiplexed primers, and probes for the following triplex: - 2019-nCoV-Orf1ab - 2019-nCoV-S - MS2 bacteriophage as an RNA extraction and RT-PCR control	(no info)	(no info)	Commercially available.	(no info)	$300 for 10 strips + $5,950 for PCR Thermocycler + $450 for sample prep kit
Conventional and Real Time RT-PCR	Genekam[179,180] Germany	4 Feb 2020	5 options: 1. Conventional PCR 2. Real Time PCR for nCoV only[181] 3. Multiplex Real Time PCR for nCoV + other Bat CoV[182] 4. Multiplex Real Time PCR for nCoV + other Bat CoV + MERS[183] 5. Multiplex Real Time PCR for nCoV + Influenza A[184]	(no info)	(no info)	In development as of 6 Feb 2020	126 min 15 s[181,183] or 120 min[182,184] of cycle time	€ 599[180] € 699[180] € 799[180] € 999[180] € 899[180]
Real-time RT-PCR	Thermo Fisher Scientific[177,185-187] USA	4 Feb 2020	**TaqPath COVID-19 Combo Kit (previously TaqMan 2019-nCoV Assay Kit)** Real-time RT-PCR kit assays specifically target all 44 complete genomes currently available at GISAID, and do not target any of the 2,116 complete genomes of other coronaviruses currently available at NCBIm.	100% (60/60) 30 nasopharyngeal swab specimens and 30 bronchoalveolar lavage specimens were spiked with extracted SARS-CoV-2 viral genomic RNA (2x to 5x LoD) to form 60 contrived positive samples.[187]	100% (60/60) 30 nasopharyngeal swab specimens and 30 bronchoalveolar lavage specimens were used as negative controls.[187]	Commercially available. Received CE Mark for IVD 26 Mar 2020.[188] Obtained EUA approval from US FDA 13 Mar 2020.[186] Obtained HSA provisional approval on 20 March 2020. Approved for inclusion	36 min cycle time per gene target	(by quote)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Tests for three gene targets: ORF1ab, N, & S.			on the Australian Register of Therapeutic Goods on 24 March 2020.		
Real-time RT-PCR	US CDC[17,189,190] USA	4 Feb 2020	**Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel** Tests for three gene targets: N1, N2, and N3 (subsequently removed[190]) plus 1 human RNase P gene control.	100% (!3/13) 117 respiratory specimens collected from 46 subjects tested with two analytically validated real-time RT-PCR assays for N4 and N5 gene targets.[189]	100% (104/104) 117 respiratory specimens collected from 46 subjects tested with two analytically validated real-time RT-PCR assays for N4 and N5 gene targets.[189]	Available to laboratories designated by CDC as qualified, and in the US, certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. Available to qualified international laboratories. Not available to U.S. hospitals or other primary care settings. Obtained EUA approval from US FDA 4 Feb 2020.	(no info)	(no info)
RT-PCR	Livzon[191]	4 Feb 2020	**Novel coronavirus (2019-nCoV) nucleic acid diagnostic kit (PCR-fluorescence method)** Detection of ORF1ab and N genes.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China's NMPA on 27 Jan 2020	30 minutes[192]	(no info)
qPCR	Coyote Bioscience[128,177] China	4 Feb 2020	**2019-nCoV Prep Free QPCR Assay** Runs on the Mini8 Portable Molecular Diagnostic QPCR Station (CFDA approved)	(no info)	(no info)	Available. Reportedly being used in China in over 30 hospitals, 16 local CDC offices, and 8 airports.	1 hr	(no info)
Microfluidic	Shenzhen Shineway Technology[193,194] (collaboration with HKUST) Hong Kong	6 Feb 2020	Novel silicon-based micro-heater, which has lower thermal mass and a better thermal conductivity, could speed up temperature rises to around 30ºC per second, greatly reducing the detection time compared to conventional PCR devices which has an average of 4-5ºC per second.	(no info)	(no info)	Available. In use by the Centers for Disease Control and Prevention (CDCP) in Shenzhen and Guangzhou with two more sets being delivered to the CDCP in Hubei and Nansha.[194]	40 min	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						Device already has CE Mark and is qualified for export to all European Union (EU) countries as well as Hong Kong.[193]		
RT-PCR	Acumen Research Laboratories[195] Singapore	7 Feb 2020	**Acu-Corona™ 2.0/3.0** With specific gene targets.	(no info)	(no info)	Prototype developed. Acu-Corona 2.0 obtained Provisional Authorisation from Singapore Health Sciences Authority on 31 March 2020. Acu-Corona 3.0 obtained Provisional Authorisation from HSA on 14 April 2020. (HSA authorisation for Acu-Corona 2.0: [196] HSA authorisation for Acu-Corona 3.0:[197] Currently CE-IVD pending and approved for research only, seeking approval from US Food and Drug Authorisation	Allows up to 94 patient samples per 1.5h	(no info)
Microfluidic	QIAGEN[198-200] The Netherlands	10 Feb 2020	**QIAStat-Dx Respiratory SARS-CoV-2 Panel [Plus]** Tests for two gene targets: ORF1b recommended by the Chinese CDC and N recommended by the US CDC.	100% (30/30) Evaluated using 10 positive clinical samples and 20 low positive contrived samples (1x–2x LOD) from retrospective nasopharyngeal swab clinical specimens in transport medium.[200]	100% (30/30) Evaluated using 30 negative samples from retrospective nasopharyngeal swab clinical specimens in transport medium.[200]	Commercially available. Obtained EUA approval from US FDA 30 Mar 2020.[199]	About an hour (Press release:[201])	(by quote)
(no info)	Public Health England[202] UK	10 Feb 2020	Real time RT-PCR (RdRp gene) assay which employs the use of two probes; one which detects 2019-nCoV, SARS-CoV and bat-SARS-related-CoVs, and the other	(no info)	(no info)	Available (non-commercially) to 9 labs across the UK.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			2019-nCoV only. The assay will be evaluated on the ABI 7500 Fast real-time PCR system.[203]					
RT-PCR [Point-of-Care]	Cepheid[27,204,205] (Plus collaboration with Sherlock Biosciences)[129] USA	10 Feb 2020	**SAR-CoV-2 Xpert Xpress** Cartridge-based nucleic acid amplification test. Tests for two gene targets: N2 & E.	100% (30/30) 30 nasopharyngeal swab specimens were spiked with SARS-CoV- (2x to 5x LoD) serving as contrived positive samples.[205]	100% (35/35) 35 nasopharyngeal swab specimens serving as negative controls.[205]	Commercially available. Obtained EUA approval from US FDA 21 Mar 2020.[27] Approved for inclusion on the Australian Register of Therapeutic Goods on 22 March 2020. [206]	45 min	(no info)
Real-time PCR and microarray technologies [Point-of-Care]	Mobidiag[207] (collaboration with Autobio Diagnostics, China) Finland	10 Feb 2020	**Novodiag** Cartridge-based qPCR system, fully automated, allowing the rapid detection of both novel coronavirus and influenzas in around 30 minutes. Two gene targets for SARS-CoV-2 (orf1ab and N)[208]	(no info)	(no info)	In development.	Less than an hour	(no info)
Immunoassay [Point-of-Care]	Sona Nanotech[209] (collaboration with GE Healthcare Life Sciences, The Native Antigen Company, Bond)[210] [211] Canada	10 Feb 2020	Proprietary nanotechnology lateral flow test using antigens specific to SARS-CoV-2 produced at Native's Oxford facility using proprietary mammalian VirtuE expression system.	(no info)	(no info)	In development.	5-15 min	<$50
LAMP [Point-of-Care]	HiberGene Diagnostics[212,213] (collaboration with distribution partner in Shenzhen, China, Medcaptain Medical Technologies) Ireland	11 Feb 2020	**Loop-mediated isothermal amplification (LAMP)-based Coronavirus test** Allows for rapid near-patient testing	(no info)	(no info)	In development using the template of existing CE-marked Flu and RSV respiratory tests.	60-70 min (including patient sample preparation time)[213]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
(no info) [Point-of-Care]	QuantuMDx[128] UK	12 Feb 2020	(no info)	(no info)	(no info)	(no info)	(no info)	(no info)
qPCR [Point-of-Care]	Molbio Diagnostics[128] India	12 Feb 2020	**qPCR Truenat Beta CoV [214]** Potentially real-time PCR then detection of wavelengths of fluorescent signal.	100% [215]	100% [215]	Available. Approved by the Indian Council of Medical Research for coronavirus testing in India on 4 April 2020.[216]	55 min	Rs 1,000 – Rs 1,500) [216]
qPCR [Point-of-Care]	OnSiteGene[128] (San Diego-based subsidiary of Singapore's Star Array) USA	12 Feb 2020	**Star Array 2019 Novel Coronavirus (SARS-CoV-2) Nucleic Acid Detection Kit 1.0** 2019-nCoV rRT-PCR kit for use on existing Peak V, that performs spatial thermal cycling using a heated liquid metal for direct amplification without the need for sample prep. Genes detected are the SARS-CoV-2 N gene and ORF1ab gene. [217]	(no info)	(no info)	Developed. Currently seeking collaborators to perform clinical tests in China and the US.[217]	10 min	(no info)
RT-PCR	TIB-Molbiol[164,218] (distributed by Roche) Germany	12 Feb 2020	**2019-nCoV Real-Time Reverse Transcription PCR Kit** Tests for three gene targets: E, RdRp, and N.	(no info)	(no info)	Available. Orders for the kit have been placed from World Health Organisation, national health authorities and laboratories in about 60 countries. [218]	(no info)	About €160[218]
RT-PCR	AusDiagnostics[219-221] Australia	16 Feb 2020	**AusDiagnostics respiratory virus panel (including SARS-CoV-2) test** Multiplex panel. Tests for two gene targets: ORF1a & ORF8	100%[221]	100%[221]	Commercially available. Received CE Mark Mar 2020.[221] Approved for inclusion in Australia's ARTG.[79]	3 hr[220]	(no info)
RT-PCR	Seegene[222,223] South Korea	18 Feb 2020	**Allplex 2019-nCoV Assay**	100% (49/49) from upper respiratory specimens	94% (94/100) from upper respiratory specimens	Commercially available.	1 hour 50 minutes after extraction [224]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Single-tube assay that tests for three gene targets: E, RdRp, and N.	(nasopharyngeal/ oropharyngeal swabs) 100% (49/49) from lower respiratory specimens (sputum)[224]	(nasopharyngeal/ oropharyngeal swabs) 97.87% (92/94) from lower respiratory specimens (sputum) [224]	Obtained EUA approval from Korean FDA 12 Feb 2020.[173,225] Product already has CE Mark for IVD. Obtained HSA provisional approval on 2 April 2020, supplied through All Eights (Singapore) Pte Ltd. [226] Approved for inclusion on the Australian Register of Therapeutic Goods on 27 March 2020 [206] FDA EUA issued 21/04/2020		
RT-PCR [Point-of-Care]	Credo Diagnostics Biomedical[227,228] Singapore	21 Feb 2020	**VitaPCR SARS-CoV-2 Assay** Runs on Credo's VitaPCR automated point-of-care molecular testing platform.	(no info)	(no info)	Commercially available. Received CE Mark 17 Mar 2020. Submitted to US FDA for EUA approval. Has provisional authorisation from Singapore's HSA.	20 min	(no info)
0(RT-PCR)	CapitalBio[43] (collaboration with Tsinghua University and West China Hospital of Sichuan University) China	24 Feb 2020	Detection of six common respiratory viruses including SARS-CoV-2 within 1.5 hours using samples of patients' oral and pharyngeal Secretions.	(no info)	(no info)	Available. Approved by China's NMPA.	1 hr 30 min	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
Real-time RT-PCR	SolGent[173,225,229] South Korea	28 Feb 2020	**DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit** Tests for two gene targets: Orf1a and N.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 27 Feb 2020.[173,225] Received CE Mark for IVD.	2 hr PCR	(no info)
Real-time RT-PCR	SD Biosensor[173,225] South Korea	28 Feb 2020	**STANDARD M n-CoV Real-Time Detection Kit** Tests for two gene targets: E and RdRp.	Sensitivity: 100% (30/30) [230]	Specificity: 100% (30/30) [230]	Available. Obtained EUA approval from Korean CDC 27 Feb 2020.[173,225] FDA EUA issued on 23/04/2020	90 min [231]	(no info)
RT-PCR	Osang Healthcare[232,233] (partnership with Italy's ELITech Group) South Korea	3 Mar 2020	**GeneFinder COVID-19 Plus RealAmp Kit** Tests for three gene targets: RdRp, E, and N. Runs on all major PCR cyclers as well as on the Sample-to-Result Platform ELITe InGenius.	100% for both upper and lower respiratory tract samples Evaluated using 30 nasopharyngeal swabs (upper respiratory tract) and sputum (lower respiratory tract) specimens spiked with SARS-CoV-2 virus (1x to 4x LoD) serving as contrived positive samples [234]	100% for both upper and lower respiratory tract samples Evaluated using 30 nasopharyngeal swabs and sputum specimens serving as negative controls[234]	Available. Received CE Mark for IVD. Obtained EUA approval from US FDA on 18 April 2020. [234]	About 120 minutes [234]	(no info)
Real-time RT-PCR	Integrated DNA Technologies (IDT)[24,174] USA	3 Mar 2020	**2019-nCoV CDC EUA Kit** Follows US CDC protocol to test for 3 N gene targets, and 1 human RNase P gene as control.	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 3 Mar 2020 for lot number #0000500383.	(no info)	USD $125[24] for 500 rxn
RT-PCR [Point-of-Care]	Mesa Biotech[28,30,235-237] USA	4 Mar 2020	**Accula SARS-Cov-2 Test** Automated PCR test for the qualitative visual detection of nucleic acid from the SARS-CoV-2 virus that runs on the Accula system machines.	100% (30/30) 30 nasopharyngeal swabs spiked with SARS-CoV-2 RNA (2x to 50x LoD) serving as	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[237]	Commercially available. Obtained EUA approval from US FDA 23 Mar 2020.	30 min	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				contrived positive samples.[237]				
RT-PCR	Luminex[238-240] USA	4 Mar 2020	**NxTag CoV Extended Panel** Multiplex panel that can be run on Luminex's MAGPIX System together with optional NxTag Respiratory Pathogen Panel. Tests for three gene targets: ORF1ab, E, & N	100% (30/30) 30 nasopharyngeal swabs spiked with purified SARS-CoV-2 viral genomic RNA (2x to 5x LoD) serving as contrived positive samples.	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.	Commercially available. Obtained EUA approval from US FDA 27 Mar 2020.	4 hr (2 hr 15 min to 2 hr 25 min cycle time)	(no info)
Real-time RT-PCR	Luminex[239-242] USA	4 Mar 2020	**ARIES SARS-CoV-2 Assay** Tests for two gene targets: ORF1ab & N	100% (30/30) 30 nasopharyngeal swabs spiked with purified SARS-CoV-2 viral genomic RNA (2x to 5x LoD) serving as contrived positive samples.[242]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[242]	Commercially available. Obtained EUA approval from US FDA 3 Apr 2020.	2 hr	(no info)
Real-time RT-PCR	Genomica[153,243] Spain	6 Mar 2020	**qCOVID-19** Real-time RT-PCR	Reported **100%.**[243] Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Reported **100%.**[243] Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Available. Received CE Mark 6 Mar 2020.[153]	(no info)	(no info)
Real-time RT-PCR	Avellino Lab[244-246] USA	9 Mar 2020	**AvellinoCoV2 test** Tests for two gene targets from US CDC protocol: N1 & N3	100% (30/30) 30 oropharyngeal and nasopharyngeal swab specimens spiked with whole SARS-CoV-2 viral RNA (1x to 100x LoD) serving as contrived positive samples.[246]	100% (30/30) 30 oropharyngeal and nasopharyngeal swab specimens serving as negative controls.[246]	Commercially available. Obtained EUA approval from US FDA 25 Mar 2020.[244]		(no info)
Real-time RT-PCR	Wadsworth Center, New York State Department of Public Health[247,248] USA	10 Mar 2020	**New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel** Tests for two gene targets: N1 & N2.	(42/43) For the easyMAG extraction, 43 individual sputum samples were spiked with the extracted whole SARS-CoV-2 virus genomic RNA (2x to 200x LoD) to serve as contrived positive samples. Testing was	(29/29) For the easyMAG extraction, 30 individual sputum samples were used but 1 was invalidated, leaving 29 samples. Testing was also done with eMAG and EZ1 extraction.[248]	Available. Obtained EUA approval from US FDA for use in Wadsworth Center, New York State Public Department of Health, and the New York City Department of Health and Mental Hygiene,	42 min 45 s cycle time per gene target	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				also done with eMAG and EZ1 extraction.[248]		Public Health Laboratories.		
RT-PCR	LGC Biosearch Technologies[25,249]	10 Mar 2020	**2019-nCoV CDC Probe and Primer Kits for SARS-CoV-2** Lot numbers #143503 and #143764	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 10 Mar 2020 for lot number #143503 and #143764.	(no info)	USD $230 for 1000 rxn[249]
Microfluidic	GenMark Diagnostics[159,250,251] USA	11 Mar 2020	**ePlex SARS-CoV-2** Automated single cartridge using digital microfluidics.	100% (17/17) 65 fresh nasopharyngeal swab specimens from 3 clinical site2s were compared with one of two brands of established comparator assay.[159]	97.9% (47/48) 65 fresh nasopharyngeal swab specimens from 3 clinical site2s were compared with one of two brands of established comparator assay.[159]	Commercially available. Obtained EUA Approval 19 Mar 2020.[251]	Less than 2 hours[252]	(no info)
RT-PCR	Fulgent Genetics[253] USA	11 Mar 2020	**COVID-19 Virus Testing by RT-PCR**	Reported 95% sensitivity.	(no info)	Submitted to US FDA for EUA Approval. Commercially Available[254]	(no info)	(no info)
NGS	Fulgent Genetics[253] USA	11 Mar 2020	**Kiloplex PCR Plus NGS** Next-generation sequencing using thousands of PCR primers to amplify sample viral genetic material before sequencing on the Illumina platform.	Undergoing validation by joint venture Fujian Fujun Gene Biotech.	Undergoing validation by joint venture Fujian Fujun Gene Biotech.	Available. Soon to be submitted to US FDA for EUA Approval.	4 hr	(by quote)
RT-PCR	bioMérieux[255-257] (subsidiary BioFire Defense) France	11 Mar 2020	**BioFire COVID-19 test** Fully automated and designed to run on FILMARRAY® 2.0 and FILMARRAY® TORCH platforms. Tests for two gene targets: ORF1ab & ORF8	100% (30/30) 30 nasopharyngeal swab specimens were spiked with live SARS-CoV-2 virus (1x to 100x LoD) serving as contrived positive samples.[258]	100% (66/66) 66 clinical nasopharyngeal swab specimens serving as negative controls.[258]	Commercially available. Obtained EUA approval from US FDA 24 Mar 2020.[257]	45 min	(no info)
Real-time RT-PCR	NeuMoDx[259-261]	12 Mar 2020	**NeuMoDx™ SARS-CoV-2 Assay** Real-time RT-PCR for use on fully automated NeuMoDx™ 288 and 96 Molecular Systems.	100% (87/87) 87 clinical nasopharyngeal swab specimens were spiked with SARS-CoV-2	100% (82/82 82 clinical nasopharyngeal swab specimens serving as negative controls.[261]	Commercially available. Obtained EUA approval from US FDA 30 Mar 2020.[259]	80 min	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Tests for two gene targets: Nsp2 & N.	genomic RNA (1x to 8x LoD) serving as contrived positive samples.[261]				
Microfluidic	Fluidigm[262] USA	16 Mar 2020	Aimed at using Fluidigm's Biomark HD system and microfluidics technology, to develop integrated fluidic circuits for parallel assays.	(no info)	(no info)	In development.	(no info)	(no info)
RT-PCR	Hologic[263-265] USA	16 Mar 2020	**Panther Fusion SARS-CoV-2 Assay** Test for two conserved regions of the ORF1ab gene	100% (69/69) 69 remnant clinical nasopharyngeal specimens were spiked with inactivated cultured SARS-CoV-2 virus (1x to 5x LoD) serving as contrived positive samples.[265]	100 (109/109) 109 remnant clinical nasopharyngeal specimens serving as negative controls.[265]	Commercially available. Obtained EUA approval from US FDA 16 Mar 2020. Approved for inclusion into the Australian Register of Therapeutic Goods on 20 March 2020.[79]	Can generate results in 3 hours[266]	(no info)
RT-PCR	LabCorp (Laboratory Corporation of America)[264,267] USA	16 Mar 2020	**COVID-19 RT-PCR Test** Test for three gene targets: N1, N2, & N3	100% (80/80) 40 nasopharyngeal swab specimens and 40 bronchoalveolar lavage specimens were spiked with quantitated live SARS-CoV-2 (1x to 8x LoD) to form 80 contrived positive samples.[267]	100% (100/100) 50 nasopharyngeal swab specimens and 50 bronchoalveolar lavage specimens serving as negative controls.[267]	Commercially available. Obtained EUA approval from US FDA 16 Mar 2020.	Approximately 2-4 days from the date of pickup of a specimen for testing to the release of the test result to the health care provider [268]	(no info)
RT-PCR	Quidel[269,270] USA	17 Mar 2020	**Lyra SARS-CoV-2 Assay** Identification of the SARS-CoV-2 virus occurs by the use of target specific primers and fluorescent-labeled 102 probes that hybridize to a conserved region of the non-structural Polyprotein (pp1ab) of the SARS-CoV-2 virus.[271]	100% (92/92) 92 nasopharyngeal swab specimens were spiked with SARS-CoV-2 RNA (1x to 5x LoD) serving as contrived positive samples.[270]	(100% (92/92) 92 nasopharyngeal swab specimens serving as negative controls.[270]	Commercially available. Obtained EUA approval from US FDA 17 Mar 2020.	45 min cycle time per gene	(no info)
RT-PCR	Quests Diagnostics[272,273] USA	17 Mar 2020	**Quest SARS-CoV-2 rRT-PCR** Tests on two gene targets: N1 & N3	100% (30/30) 12 pairs of nasopharyngeal swab	100% (72/72) 72 presumed-negative nasopharyngeal/throat	Commercially available.	58 min 40 s cycle time per gene	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				and sputum specimens from **actual COVID-19 patient** formed 24 samples, together wiith 6 additional randomly selected to be duplicated, serving as total 30 positive samples.[273]	swab specimens from before Oct 2019 servings as negative controls.[273]	Obtained EUA approval from US FDA 17 Mar 2020.		
Real-time RT-PCR	Becton Dickinson (BD)[274-276] USA	17 Mar 2020	**BioGX SARS-CoV-2 Reagents for BD MAX System** Tests for two gene targets: N1 & N2	100% (29/29) 30 retrospective collected clinical nasopharyngeal swab specimens spiked with quantified genomic RNA of SARS- CoV-2 (1x to 5x LoD) serving as contrived positive samples. 1 sample removed from data analysis.[274]	100% (30/30) 30 retrospective collected clinical nasopharyngeal swab specimens serving as negative controls.[274]	Commercially available. Obtained EUA approval from US FDA 2 Apr 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 17 April 2020.[79]	2 hr	(no info)
RT-PCR	Abbott Molecular[27,277,278] USA	18 Mar 2020	**Abbott RealTime SARS-CoV-2 assay** Will run on the Abbott m2000 RealTime system. Tests for two gene targets: RdRp & N.	100% (60/60) 61 nasopharyngeal swabs spiked with recombinant virus containing SARS-CoV-2 RNA sequences (1x to 20x LoD) serving as contrived positive samples. 1 sample was invalidated and excluded.[278]	100% (31/31) 34 nasopharyngeal swabs serving as negative controls. 3 samples were invalidated and excluded.[278]	Commercially available. Obtained EUA approval from US FDA 18 Mar 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 17 April 2020.[206] Date of HAS Provisional Authorisation: 01/04/2020 [279]	(no info)	(no info)
RT-PCR	DiaSorin Molecular[280-282] Italy	19 Mar 2020	**Simplexa COVID-19 Direct** Will run on the DiaSorin's LIAISOn MDX thermocycler. Tests for two gene targets: S & ORF1ab.	100% (52/52) 108 fresh nasopharyngeal swab specimens from 3 clinical site2s were	100% (56/56) 108 fresh nasopharyngeal swab specimens from 3 clinical sites were	Commercially available. Obtained EUA approval from US FDA 19 Mar 2020.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				compared with one of two brands of established comparator assay.[282]	compared with one of two brands of established comparator assay.[282]			
ddPCR	Bio-Rad Laboratories[283-285] USA	19 Mar 2020	**COVID-19 Droplet Digital PCR (ddPCR) Assay** Quantitative assay for use on Bio-Rad's QX200 and QXDx Droplet Digital PCR Systems.	Reported enhanced sensitivity.[284]	(no info)	Commercially available. EUA Submission Pending[286]	(no info)	(by quote)
Real-time RT-PCR	Maccura Biotechnology[244,287,288] China	22 Mar 2020	**SARS-CoV-2 Fluorescent PCR Kit** Tests for three gene targets: ORF1ab, N, & E.	100% (30/30) 15 nasopharyngeal and 15 oropharyngeal swab samples from suspected cases that tested negative had additional aliquot spiked with SARS-CoV-2 whole genomic RNA (2x to 5x LoD) serving as 30 contrived positive samples.[288]	100% (30/30) 15 nasopharyngeal and 15 oropharyngeal swab samples from suspected cases that tested negative had additional aliquot serving as 30 negative controls.[288]	Commercially available. Received CE Mark in Mar 2020.[287] Obtained EUA approval from US FDA 15 Apr 2020.	37 min 10 s cycle time per gene target	(no info)
RT-PCR	DiaCarta[289,290] USA	23 Mar 2020	**QuantiVirus SARS-CoV-2** Tests for two gene targets: N, ORF1ab, & E	96.7% Clinically validated in the company's CLIA-certified lab in Richmond, California.	100% Clinically validated in the company's CLIA-certified lab in Richmond, California.	Commercially available. Received CE Mark for IVD Mar 2020. Obtained EUA approval from US FDA 8 Apr 2020.[247]	(no info)	(no info)
RT-PCR	PerkinElmer[28,291,292] USA	24 Mar 2020	**PerkinElmer New Coronavirus Nucleic Acid Detection Kit** Tests for two gene targets: N & ORF1ab.	100% (47/47) 47 oropharyngeal and nasopharyngeal swab specimens spiked with inactivated SARS-CoV-2 virus (1x to 5x LoD) serving as contrived positive samples.[292]	100% (94/94) 94 oropharyngeal and nasopharyngeal swab specimens serving as negative controls.[292]	Commercially available. Obtained EUA approval from US FDA 24 Mar 2020. EUA amendment on April 1st to add an additional nucleic acid extraction method which utilizes the chemagic Viral DNA/RNA 300 Kit H96	104 min 30s cycle time per gene target.	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						on a new extraction platform, the chemagic 360 equipped with the chemagic Rod Head Set 96; and (2) make other minor changes and edits to the IFU labeling was granted on 01/04/2020 [293]		
Microfluidics [Point-of-Care]	Abbott Diagnostics[29,294] USA	27 Mar 2020	**ID Now COVID-19 test** Automated assay that runs on Abbott's ID Now platform.	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 27 Mar 2020.	5-13 min (5 min for positive results, 13 min for negative results)	(no info)
Real-time RT-PCR	Ipsum Diagnostics[295,296]	1 Apr 2020	**COV-19 IDx assay** N1 gene target	100% (36/36) 36 nasopharyngeal swabs spiked with BEI ATCC Genomic RNA from SARS Related Coronavirus 2 (not actual clinical sample) serving as contrived positive samples.[296]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[296]	Commercially available. Obtained EUA approval from US FDA 1 Apr 2020.	(no info)	(no info)
Real-time RT-PCR	Gnomegen[297,298] (Subsidiary of QuestGenomics) USA (China)	6 Apr 2020	**Gnomegen COVID-19 RT-Digital PCR Detection Kit** Tests for two gene targets: N1 & N2	100% (30/30) 30 oropharyngeal swabs spiked with quantified SARS-CoV-2 whole viral RNA (1x to 5x LoD) serving as contrived positive samples.[298]	100% (30/30) 30 oropharyngeal swabs serving as negative controls.[298]	Commercially available. Obtained EUA approval from US FDA 6 Apr 2020.	129 min 30 s cycle time	(no info)
Real-time RT-PCR	InBios International[190,299,300] USA	7 Apr 2020	**Smart Detect SARS-CoV-2 rRT-PCR Kit** multiplex one-step rRT-PCR that can run on CFX96 Touch Real-Time PCR. Tests for three gene targets: N, E, & ORF1b	100% (30/30) 30 nasopharyngeal swabs spiked with SARS-CoV-2 viral genomic RNA (1x to 5x LoD) serving as contrived positive samples.[299]	96.7% (29/30) 30 nasopharyngeal swabs serving as negative controls.[299]	Commercially available. Obtained EUA approval from US FDA 7 Apr 2020.	4 hr[300] (43 min 45 s cycle time for each gene)[299]	(no info)
RT-PCR	Genetron Health[301] China	7 Aor 2020	**Detection Kit for Novel Coronavirus (SARS-CoV-2) RNA**	(no info)	(no info)	Commercially available.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						Received CE Mark 7 Apr 2020. Submitted to US FDA for EUA approval.		
Real-time RT-PCR	Becton Dickinson (BD)[302,303] USA	8 Apr 2020	**BD SARS-CoV-2 Reagents for BD MAX System** Tests for two gene targets: N1 & N2	96% (48/50) 50 retrospective collected clinical nasopharyngeal swabs spiked with quantified genomic RNA of SARS-CoV-2 (1x to 5x LoD) serving as contrived positive samples.[303]	100% (29/29) 29 retrospective collected clinical nasopharyngeal swab specimens serving as negative controls.[303]	Commercially available. Obtained EUA approval from US FDA 8 Apr 2020.	(no info)	(no info)
LAMP	Atila BioSystems[264,304,305] USA	10 Apr 2020	**iAMP COVID-19 Detection Kit** Real-time fluorescent reverse transcription isothermal amplification **without requiring RNA extraction and can run up to 94 samples simultaneously.**[304,305] Tests for two gene targets: N & ORF1ab.	100% (35/35) 35 oropharyngeal swabs from healthy individuals spiked with iAMP COVID-19 Sample Buffer Mix (2x to 10x LoD) serving as contrived positive samples.[304]	100% (40/40) 40 oropharyngeal swabs from healthy individuals serving as negative controls.[304]	Commercially available. Obtained EUA approval from US FDA 10 Apr 2020.	51 min	(by quote)
RT-PCR Kit	Genosensor, LLC[306]		**GS COVID-19 RT-PCR Kit** Real-time reverse transcription polymerase chain reaction test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs, nasal swabs, mid-turbinate swabs from individuals suspected of COVID-19. Positive results are indicative of the presence of SARS-CoV-2 RNA.	100% (32/32)	100% (32/32)	Available. EUA issued on 16th April 2020.	(no info)	(no info)
RT-PCR Kit	KorvaLabs Inc.[307]		**Curative-Korva SARS-CoV-2 Assay**	100% (5/5)	100% (5/5)	Available. EUA issued on 16th April 2020.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, nasal swab, and oral fluid specimens from individuals suspected of COVID-19. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.					
RT-PCR Kit	Genosensor, LLC [306]		**GS COVID-19 RT-PCR Kit** Real-time reverse transcription polymerase chain reaction test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs, nasal swabs, mid-turbinate swabs from individuals suspected of COVID-19. Positive results are indicative of the presence of SARS-CoV-2 RNA.	100% (32/32)	100% (32/32)	Available. EUA issued on 16th April 2020.	(no info)	(no info)
RT-PCR Kit	KorvaLabs Inc. [307]		**Curative-Korva SARS-CoV-2 Assay** Real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, nasal swab, and oral fluid specimens from individuals suspected of COVID-19. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in	100% (5/5)	100% (5/5)	Available. EUA issued on 16th April 2020.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.					
RT-PCR Kit	Fosun Pharma USA Inc.[308]		**COVID-19 RT-PCR Detection Kit** Real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper and lower respiratory specimens (such as anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals suspected of COVID-19. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper and lower respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.	100% (50/50)	100% (100/100)	Available. EUA issued on 17th April 2020	(no info)	(no info)
RT-PCR	Mobidiag[208] Finland		**Amplidiag COVID-19** Real-time RT-PCR test with two molecular targets (orf1ab and N) including at least one conserved region and one specific region to mitigate effects of genetic drift and avoid cross-reaction with other endemic coronaviruses.	(no info)	(no info)	Available as an emergency use test in Finland and France, set up for routine use in main clinical laboratories in Finland with capacity to test up to 4000 samples a day.[309] In the process for obtaining emergency	48 samples in <3h	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						use authorisation in Sweden and the UK. In the process for obtaining CE-IVD.		
Immunoassay for SARS-CoV-2 antigens	SD Biosensor [51] South Korea		**STANDARD Q COVID-19 Ag** Rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in the human nasopharynx	(no info)	(no info)	Available. Obtained CE certification	30 minutes	(no info)
Immunoassay for SARS-CoV-2 viral nucleoprotein antigens	SD Biosensor [310] South Korea		**STANDARD F COVID-19 Ag FIA** Fluorescent immunoassay to detect SARS-CoV-2 infection in human nasopharyngeal swab specimen by identifying the existence of SARS-CoV-2 viral nucleoprotein antigens	Higher sensitivity than rapid test	(no info)	Available. Obtained CE certification	30 minutes	(no info)
RT-PCR	Genetic Signatures Ltd Australia		**EasyScreen™ SARS-CoV-2 Detection Kit** Real time PCR which enables qualitative detection of SARS-CoV-2 via two targets (SARS-CoV-2 N and E genes)	(no info)	(no info)	Available. CE-IVD marked.[311] Approved for inclusion into the Australian Register of Therapeutic Goods on 13 April 2020.[206]	(no info)	(no info)
RT-PCR	Shanghai ZJ Bio-Tech Co Ltd (also called Liferiver)[312] China		**Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes)** Qualitative detection of SARS-CoV-2 by real time PCR	(no info)	(no info)	Available. Approved for inclusion into the Australian Register of Therapeutic Goods on 22 March 2020.[206]	(no info)	
RT-PCR	AITbiotech Pte Ltd[313]		**abTES™ COVID-19 qPCR I Kit** Qualitative RT-PCR which detects two COVID-19	(no info)	(no info)	Date of Provisional Authorisation by HSA: 05/03/2020	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	Singapore		specific regions from its non-structure polypeptide					
RT-PCR	DSO National Laboratories[314] Singapore		**Real-Time PCR Assay for the Detection of SARSCoV-2 Virus** RT-PCR based on specific detection of the polymerase gene region in SARS-CoV-2 virus.	(no info)	(no info)	Date of Provisional Authorisation by HSA: 10/03/2020	(no info)	(no info)
RT-PCR	Biowalker Pte Ltd[315] Singapore		**Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)** Detection of 2019-nCoV RNA in swab and sputum samples	(no info)	(no info)	Date of Provisional Authorisation by HSA: 24/03/2020	(no info)	(no info)
RT-PCR	JN Medsys Pte Ltd[316] Singapore		**ProTect™ COVID-19 RT-qPCR Kit** In-vitro qualitative detection of SARS-CoV-2 from samples. The test targets SARS-CoV-2 N1, N2 and N3 genes and the human RNase P control gene.	High sensitivity and specificity, no statistics given	(no info)	Date of Provisional Authorisation by HSA: 19/03/2020	Within 2 hours[317]	(no info)
RT-PCR	Veredus Laboratories Pte Ltd[167] Singapore		**VereCoV™ Detection Kit** Multiplex RT-PCR/microarray-based in-vitro diagnostic test.			Date of Provisional Authorisation by HSA: 18/02/2020		
RT-PCR	Vela Operations Singapore Pte Ltd[318] Singapore		**ViroKey SARS-CoV-2 RT-PCR Test**	(no info)	(no info)	Date of Provisional Authorisation by HSA: 15/04/2020	(no info)	(no info)
RT-PCR	SPD Scientific Pte Ltd[319] Singapore		**Cepheid® Xpert® Xpress SARS-CoV-2**	(no info)	(no info)	Date of Provisional Authorisation by HAS: 26/03/2020	(no info)	(no info)
RT-PCR	PerkinElmer Singapore Pte Ltd [320]		**PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay**	(no info)	(no info)	Provisional Authorisation from HSA: 20/04/2020	(no info)	(no info)
RT-PCR	BioWalker Pte Ltd [321]		**BioWalker SARS-CoV-2 Assay**	(no info)	(no info)	Date of Provisional Authorisation from HSA: 20/04/2020	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
RT-PCR	Medicell Pharmaceutical (S) Pte Ltd [322]		**Sansure Biotech Novel Coronavirus (2019- nCoV) Nucleic Acid Diagnostic Kit**	(no info)	(no info)	Date of Provisional Authorisation from HSA: 23/04/2020	(no info)	(no info)
RT-PCR	Trax management Services Inc. [323]		**PhoenixDx 2019-CoV**	100% (30/30)	100% (10/10)	FDA EUA issued on 20/4/2020	(no info)	(no info)
RT-PCR	Ustar Biotechnologies (Hangzhou) Co Ltd (China) [324]		**EasyNat Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)**	(no info)	(no info)	Approved for inclusion on the Australian Register of Therapeutic Goods on 23 April 2020.	(no info)	(no info)
RT-PCR	CTK Biotech Inc (United States of America) [325]		**Aridia COVID-19 Real-Time PCR Test**	95.1%	95.9%	Approved for inclusion on the Australian Register of Therapeutic Goods on 24 April 2020.	(no info)	(no info)
RT-PCR	PCL[175]		**PCL COVID19 Ag Rapid FIA [175]** Qualitative detection of SARS-CoV-2 antigens from human oropharyngeal and deep sputum samples	Sensitivity: 100%		CE approved	10 minutes	(no info)
RT-PCR	Seasun Biomaterials [326]		**RT-PCR Test U-TOP COVID-19 Detection Kit [327]** Qualitative detection of SARS-CoV-2 antigens from oropharyngeal and nasopharyngeal swab specimens, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum samples	100% (for both nasopharyngeal and sputum)[327]	No cross-reactivity with 33 microorganisms	FDA EUA issued on 27/04/2020	(no info)	(no info)
RT-PCR assay	Rhoenix, Inc. [328]		**Rheonix COVID-19 MDx Assay[329]** Qualitative detection of total nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal	100%[329]	100%	FDA EUA issued on 29/04/2020[329]	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			(throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage (BAL) fluid.					
RT-PCR assay	LabGenomics Co., Ltd [330]		**LabGun COVID-10 RT-PCR Kit** [331] Qualitative detection of total nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal washes, nasal aspirates and sputum	100% (50/50)[331]	100% (100/100) [331]	FDA EUA issued on 29/04/2020 [331]	(no info)	(no info)
RT-PCR	BioFire Diagnostics, LLC [332]		**BioFire Respiratory Panel 2.1** [333] Multiplex RT-PCR test detecting SARS-CoV-2 spike (S) and membrane (M) gene	98% (48/49)	100% (279/279)	FDA EUA issued on 1 May 2020[333]	(no info)	(no info)
RT-PCR	Bio-Rad Laboratories, Inc. [334]		**Bio-Rad SARS-CoV-2 ddPCR Test** [335] Multiplex RT-PCR test detecting SARS-CoV-2 spike (S) and membrane (M) gene	94.87% (37/39, analysis done after Thermo MagMAX extraction); 94.59% (35/37, analysis done after QIAamp viral RNA extraction)	94.87% (37/39, analysis done after Thermo MagMAX extraction); 95.00% (38/40, analysis done after QIAamp viral RNA extraction)	FDA EUA issued on 1 May 2020 [335]	(no info)	(no info)

Table 2.2 Upcoming/Available Diagnostics: Serological tests

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgM/IgG antibody	Livzon[191] (collaboration with Wuhan Institute of	4 Feb 2020	**Diagnostics kit for IgM/IgG antibody to novel coronavirus (ELISA)**	(no info)	(no info)	Developed. Undergoing testing. Emergency use	(no info)	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
immunoassay (ELISA)	Virology, Chinese Academy of Science)		Indirect method for ELISA for in vitro qualitative detection of antibodies to SARS-CoV-2 in human serum or plasma.			approval submitted to China's NMPA on 28 Jan 2020. Approved on 14 March for commercial use. [336]		
IgM/IgG antibody immunoassay (colloidal gold)	Livzon[191] (collaboration with Wuhan Institute of Virology, Chinese Academy of Science)	4 Feb 2020	**Diagnostics kit for IgM/IgG antibody to novel coronavirus (colloidal gold)** Immunochromatography assay for in vitro qualitative detection of antibodies to SARS-CoV-2 in human serum or plasma.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China's NMPA on 2 Feb 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 23 April 2020.	15 mi	(no info)
CLIA	Shenzhen Tisenc Medical Device[53] (collaboration with Shenzhen University and Shenzhen No.3 People's Hospital) China	12 Feb 2020	**2019 Novel Coronavirus IgM kit (CLIA)** **2019 Novel Coronavirus IgG kit (CLIA)** Chemiluminescence antibody test kit using serum or plasma.	IgM kit - 96.6% (29/30) IgG kit - 96.6% (29/30)[337]	(no info)	Available. Received CE certification on 6 March 2020[337]	22 min (unclear if serum/plasma extraction time included or not)	(no info)
IgM antibody immunoassay [Point-of-Care]	Guangzhou Medical University[11,41] (Dr Zhong Nanshan) In collaboration with Jiangsu Medomics Medical Technologies and many other institutes China	15 Feb 2020	**SARS-CoV-2 rapid IgG-IgM combined antibody kit (colloidal gold)** In-vitro detection of IgG/IgM antibodies using lateral flow immunoassay techniques [338,55]	88.66% (352/397) Evaluated using blood samples from 397 clinically confirmed (including PCR test) SARS-CoV-2-infected patients.[55]	90.63% (116/128) Evaluated using blood samples from 128 non-SARS-CoV-2-infected patients.[55]	Available for use in China but not commercially	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgM/IgG antibody immunoassay	Nankai University[54] (in collaboration with	17 Feb 2020	**Novel Coronavirus (2019-nCoV) IgM/IgG antibody detection kit**	75% (30/40) in first clinical trial, but	(no info)	Available non-commercially in China. [339]	15 min (unclear if serum/plasma	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	KingFocus Biomedical) China			suboptimal in the second trial[339]			extraction time included or not)	
IgM and IgG antibody immunoassay [Point-of-Care]	Guangzhou Wondfo Biotech[42-46] China	20 Feb 2020	**Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)** Colloidal gold method for IgM and IgG antibody detection.	(no info)	(no info)	Available. Approved by China's NMPA. Received CE Mark Mar 2020.[46,47] Obtained HSA provisional approval on 9 April 2020, supplied through SkyQuest Pte Ltd.[340] Approved for inclusion on the Australian Register of Therapeutic Goods on 25 March 2020.[206]	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgG and IgA antibody immunoassay	EUROIMMUN AG[341-343] Germany	21 Feb 2020	**Anti-SARS-CoV-2 ELISA** ELISA for IgG and IgA antibody detection. S1 domain of the spike protein is used as the substrate in the ELISAs as it is considered immunogenic and is evolutionarily less conserved, leading to high specificity. [344]	Sensitivity: 90% (27/30) Specificity: 100% (80/80)[345]	IgG – 99% IgA – approximately 90%, not recommended for screening [346]	Commercially available. CE-marked since 25 March 2020 [260]	2 hours [347]	(no info)
IgG and IgM antibody immunoassay [Point-of-Care]	BioMedomics / Jiangsu Medomics Medical Technology[52,55,56] USA / China	21 Feb 2020	**COVID-19 IgM/IgG Rapid Test** Lateral flow immunoassay with both IgM and IgG antibodies adhered using colloidal gold. Can be used with fingerstick whole blood.	**88.66%** 352 positives out of 397 positive cases: - 256 both IgG and IgM - 72 IgG - 24 IgM	**90.63%** 12 positives out of 128 negative controls: - 1 both IgG and IgM - 1 IgG - 10 IgM	Commercially available. More than half a million sold in China. Received CE Mark for IVD 8 Mar 2020. Already sold in Italy.[56] Submitted to US FDA for EUA approval.[57,58]	15 min	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgM antibody immunoassay	Innovita Biological Technology[42] China	23 Feb 2020	**2019-nCoV Antibody Test (colloidal gold)** IgG and IgM antibody detection from venous whole blood/ plasma/ serum samples	87.3% [348]	100% [348]	Available commercially. Approved by China's NMPA. Approved for inclusion on the Australian Register of Therapeutic Goods.[79] CE-IVD approved. [3] Partnered with Scanwell Health to be distributed in US, together with an accompanying smartphone app, pending US FDA EUA approval. [348]	(no info)	Projected to be $70 as distributed by Scanwell Health [348]
Antibody immunoassay [Point-of-Care]	Mologic (partnership with the Institut Pasteur de Dakar)[349,350] UK	25 Feb 2020	Lateral flow immunoassay for detection of antibodies for SARS-CoV-2.	99% [351]	98%[351]	Developed. Ready for manufacture with CE mark.[351]	10 min	(no info)
IgM or IgG antibody immunoassay	Duke-NUS Medical School[39,40] (Prof Wang Linfa) Singapore	26 Feb 2020	IgM or IgG antibody detection.	(no info)	(no info)	Available (not commercially).	(no info)	(no info)
CLIA for IgM and IgG antibody	Snibe Diagnostic[352,353] China	28 Feb 2020	**Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits** Fully automated CLIA using 10µL sample volume of serum or plasma.	Differs across different durations from symptom onset <5 days: IgA – 3.3% (1/30); IgG – 10% (3/30) 5-10 days: IgA – 15.4% (2/13); IgG – 53.8% (7/13) 10-21 days: IgA – 60% (3/5); IgG – 100% (5/5)[354]	(no info)	Available. Have been distributed in China and will soon be in Italy. Received CE Mark 19 Feb 2020.[353]	30 min	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgM and IgG antibody immunoassay [Point-of-Care]	Hangzhou AllTest Biotech[79,355,356] China	2 Mar 2020	**2019-nCoV IgG/IgM Rapid Test Cassette** Lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma specimen.	IgM test **85.0%** (17/20) IgG test **100.0%** (20/20) Tested with the results compared to leading commercial PCR.	IgM test **96.0%** (48/50) IgG test **98.0%** (49/50) Tested with the results compared to leading commercial PCR.	Commercially available. Received CE Mark for IVD. Approved for inclusion in Australia's ARTG.[79] Used in study by Lee et al (2020).[357]	10 min	(by quote)
IgM and IgG antibody immunoassay [Point-of-Care]	Pharmact AG[48] Germany	10 Mar 2020	**CoV-2 Rapid Test** Using drops of blood from fingerstick onto test cassette, with two drops of buffer solution.	(no info)	(no info)	Available.	20 min	€39.95
IgM and IgG antibody immunoassay [Point-of-Care]	Zhejiang Orient Gene Biotech[49,50] China	10 Mar 2020	**COVID-19 IgG/IgM Rapid Test** Solid phase immunochromatography assay for rapid qualitative detection of IgG and IgM antibodies to SARS-CoV-2 using human whole blood, serum or plasma.	IgM test **87.9%** (87/99) IgG test **97.2%** (35/36) Tested with 113 blood samples, and the results compared to RT-PCR or clinical diagnosis.	IgM test **100%** (14/14) IgG test **100%** (14/14) Tested with 113 blood samples, and the results compared to RT-PCR or clinical diagnosis.	Available. Received CE Mark. Currently one of only a few tests used for coronavirus screening in China. Commercialisation and distribution licensing deal with Aytu Bioscience for USA. Approved for inclusion on Australia's ARTG on 1 April 2020.[79]	2-10 min	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	SD Biosensor[51] South Korea	(Webpage found as of 12 Mar 2020)	**STANDARD Q COVID-19 IgM/IgG Duo** Immunochromatography assay for rapid qualitative detection of IgG and IgM antibodies to SARS-CoV-2 using human whole blood, serum or plasma.	Sensitivity at 81.8% (27/33)[51]	Specificity at 96.7% (29/30)	Available.	10 min	(no info)
Carbohydrate-based glycation	Iceni Diagnostics[358]	20 Mar 2020	Carbohydrate-based, lateral flow assay for detection of	(no info)	(no info)	In development.	(no info)	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
pattern detection	UK		glycation patterns of SARS-CoV-2					
IgM and IgG antibody immunoassay [Point-of-Care]	Chembio Diagnostic Systems[359-361] USA	20 Mar 2020	**DPP COVID-19 IgM/IgG System** Lateral flow assay testing for IgM and IgG, to be read using the DPP Micro Reader or DPP Micro Reader 2 (not visually).	IgM: 50% (3/6) IgG: 100% (6/6) Tested with fresh, fingerstick blood samples prospectively-collected from 11 hospital workers in the United States (New York), 6 of whom were confirmed positive cases with results from FDA-authorised RT-PCR test.[360]	IgM: 100% (6/6) IgG: 100% (6/6) Tested with fresh, fingerstick blood samples prospectively-collected from 11 hospital workers in the United States (New York), 5 of whom were confirmed negative with results from FDA-authorised RT-PCR test.[360]	Commercially available. Obtained EUA approval from US FDA 14 Apr 2020.	10-15 min	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	Cellex[59,251] USA	1 Apr 2020	**qSARS-CoV-2 IgG/IgM Rapid Test** For "aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests."[59] Can be used with serum, plasmas, or whole blood from venepuncture (not fingerstick).	93.8% (120/128) Tested with 98 positive serum or plasma samples collected from individuals who tested positive with RT- PCR and 30 samples from hospitalised individuals who were clinically confirmed positive and exhibited severe symptoms.[59]	96.0% (240/250) Tested with negative serum or plasma samples collected prior to September 2019.[59]	Commercially available. Obtained EUA approval from US FDA 1 Apr 2020. Approved for inclusion in Australia's ARTG 31 Mar 2020.[79]	15-20min	(no info)
IgM and IgG antibody immunoassay	Ortho Clinical Diagnostics[362-364] USA	6 Apr 2020	**VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack** Runs on VITROS ECi/ECiQ/3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems. Can run up to 150 samples per hour.[364]	83.3% (30/36) Tested with 36 samples from patients confirmed to be SARS-CoV-2 positive with PCR.[363]	100% (400/400) 400 presumed SARS-CoV-2 negative samples from healthy blood donors serving as negative controls.[363]	Available. Obtained EUA approval from US FDA 14 Apr 2020.	48 min (Up to 150 samples per hour)	(no info)
IgG antibody immunoassay	Abbott Laboratories Inc.[365,366] USA	15 Apr 2020	**SARS-CoV-2 IgG test** Lab-based serology test for the detection of IgG. Can run on ARCHITECT® i1000SR and i2000SR laboratory instruments.	Sensitivity: 0% (Less than 3 days post symptom onset), 25% (3-7 days post symptoms onset), 86.36% (8-13 days post	Specificity: 100% (73/73) [367]	Commercially available. FDA EUA issued on 23/04/2020	(100-200 tests per hour)	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				symptoms onset), 100% (more than 14 days post symptoms onset) [367]				
IgG Antibody immunoassay	Mount Sinai Laboratory [368]		**COVID-19 ELISA IgG Antibody test** ELISA performed for the qualitative detection of human IgG antibodies in serum and plasma specimens collected from individuals suspected of prior infection with the virus that causes COVID-19. Detection of IgG SARS-CoV-2 antibodies. The presence of IgG antibodies defines IgG antibody seroconversion and generally becomes detectable beginning 10-14 days following infection.	92% (37/40)	100% (74/74)	Available. EUA issued on 15th April 2020.	(no info)	(no info)
IgG and IgM antibody immunoassay (colloidal gold) [Point-of-Care]	Mobidiag (in collaboration with Autobio Diagnostics) [208] Finland		**Anti-SARS-CoV-2 Rapid Test** Immunoassay Anti-SARS-CoV-2 Rapid Test is based on a colloidal gold method for the rapid, qualitative determination of SARS-CoV-2 IgG/IgM antibodies in human serum, plasma or whole blood.	97.4%	96.2%	CE-IVD marked. For in vitro diagnostic use. FDA EUA issued on 24/04/2020	<15 min	(no info)
IgG/IgM immunoassay	Hangzhou Realy Tech Co Ltd China		**2019-nCOV/COVID-19 IgG/IgM Rapid Test Device** Lateral flow IgG/IgM	(no info)	(no info)	Approved for inclusion on the Australian Register of Therapeutic Goods on 16 April 2020 [206]	(no info)	(no info)
IgG/IgM immunoassay	Hangzhou Clongene Biotech Co Ltd China		**COVID-19 IgG/IgM Rapid Test Cassette** Rapid point-of-care lateral flow chromatographic	IgM – 87.01% (67/77) IgG – 99.42% (75/77) [369]	IgM – 98.89% (89/90) [369]	Available. Received CE mark.[369] Approved for inclusion into the Australian	(no info)	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			immunoassay for the qualitative detective of IgG and IgM antibodies to SARS-CoV-2			Register of Therapeutic Goods on 26 March 2020 [206]		
IgG/IgM immunoassay	Hangzhou Biotest Biotech Co Ltd China		**COVID-19 IgG/IgM Rapid Test Cassette** Rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma	IgG – 100% (75/75) IgM – 91.8% (78/85)[370]	IgG – 99.5% (369/371); IgM – 99.2% (368/371)[370]	Available. Received CE mark. Approved for inclusion into the Australian Register of Therapeutic Goods on 4 April 2020. [206]	(no info)	(no info)
IgM/IgG antibody test [Point-of-Care]	Hangzhou Laihe Biotech Co Ltd[371] China		**Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)** POCT rapid SARS-CoV-2 IgM/IgG antibody test	(no info)	(no info)	Commercially available. Approved for inclusion into the Australian Register of Therapeutic Goods on 6 April 2020.[206]	Within 10 min	$20 per test kit
IgG/IgM antibody test	CTK Biotech Inc[372] USA		**OnSite COVID-19 IgG/IgM Rapid Test** Designed for initial screening by detecting anti-SAR-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood	96.9%	99.4%	Available commercially. Approved for inclusion into the Australian Register of Therapeutic Goods on 19 March 2020. [206]	10 minutes	(no info)
IgG/IgM antibody test	Qingdao Hightop Biotech Co Ltd[373] China		**SARS-CoV-2 IgM/IgG Antibody Rapid Test** Qualitative detection of SARS-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood samples	IgM – 82% IgG – 93%	IgM – 97% IgG – 97.5%	Available. Approved for inclusion into the Australian Register of Therapeutic Goods on 31 March 2020. [206]	15 minutes	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
Antibody immunoassay	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd[374] China		**Wantai SARS-CoV-2 Ab Rapid Test Kit** Rapid qualitative detection of total antibodies against SARS-CoV-2 in human serum, plasma or whole blood specimens, employing chromatographic lateral flow device in a cassette format (colloidal gold)	96.6% (131/137) Evaluated using 137 specimens from confirmed COVID-19 patients and 209 specimens from healthy individuals	95.2% (199/209) Evaluated using 137 specimens from confirmed COVID-19 patients and 209 specimens from healthy individuals	Available. CE-IVD marked. Approved for inclusion into the Australian Register of Therapeutic Goods on 27 March 2020.[206]	(no info)	(no info)
Antibody Immunoassay	Camtech Diagnostics Pte Ltd[375] Singapore		**Camtech COVID-19 IgM/IgG** Immunoassay kit for the rapid and differential detection of IgG and IgM against COVID-19 using serum, plasma and whole blood.	(no info)	(no info)	Date of Provisional Authorisation by HSA: 09/04/2020	10 Minutes	(no info)
IgG/IgM Antibody detection	Biolidics Limited[376] Singapore		**Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit** Also marketed as **Biolidics 2019-nCoV IgG/IgM Detection Kit** Detection of 2019-nCoV IgG and IgM in human serum, plasma and whole blood	(no info)	(no info)	Date of Provisional Authorisation by HSA: 20/03/2020	(no info)	(no info)
IgG/IgM Antibody detection	Everest Links Pte Ltd[377] Singapore		**VivaDiag™ COVID-19 IgM/IgG Rapid Test** In vitro diagnostic test for the qualitative determination of COVID-19's igM and IgG antibodies in human blood, serum and plasma.	(no info)	(no info)	Date of Provisional Authorisation by HSA: 20/03/2020 Date of approval for inclusion into ARTG: 26/03/2020	(no info)	(no info)
IgG/IgM Antibody detection	Grit Overseas Pte Ltd [378]		**DiagnoSure COVID-19 IgG/ IgM Rapid Test Cassette**	(no info)	(no info)	Date of Provisional Authorisation from HSA: 24/04/2020	(no info)	(no info)
IgG Antibody detection	Ortho-Clinical Diagnostics, Inc. [379]		**VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack**	87.5% (42/48)	100% (407/407)	FDA EUA issued on 24/4/2020	(no info)	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgG Antibody detection	Diasorin Inc.[380]		**LIAISON SARS-CoV-2 S1/S2 IgG**	25% (Less than 5 days from diagnosis), 89.8% (6-14 days from diagnosis), 97.56% (More than 15 days from diagnosis)	99.3% (1082/1090)	FDA EUA issued on 24/4/2020	(no info)	(no info)
IgG and IgM antibody immunoassay	Shenzen YHLO Biotech Co. Ltd (China)[381]		**iFlash 8000 CLIA analyser**[382] Fully Automated chemiluminescent immunoassay for anti-SARS-CoV-2 IgM and IgG antibodies.	Sensitivity: 81.5% for IgM, 100% for IgG[382]	Specificity: 88.1% for IgM, 92.8% for IgG[382]	(no info)	(no info)	(no info)
IgG and IgM antibody	GenBody Inc (South Korea)[323]		**GenBody COVID-19 IgM/IgG** Point-of-care chromatographic immunoassay kit for the rapid and differential detection of anti-SARS-CoV-2 IgM and IgG using serum, plasma and whole blood from capillary blood samples.[323]	Sensitivity : 50% at Day 1-6, 91.7% at after Day 7[323]	Specificity : 97.5%[323]	Availability: Approved for inclusion on the Australian Register of Therapeutic Goods on 28 April 2020.	10 minutes	(no info)
IgG and IgM antibody	Healgen Scientific Limited Liability Company (USA)[383]		**COVID-19 Antibody Rapid Detection Kit**[383] Rapid test for the qualitative, differential detection of both anti-SARS-CoV-2 IgM and IgG antibodies from whole blood, serum and plasma, using lateral flow method	Sensitivity: IgG 97.2%; IgM 87.9%	Specificity: IgG 100%; IgM 100%	Approved for inclusion on the Australian Register of Therapeutic Goods on 29 April 2020. Pending FDA approval	10 minutes	(no info)
IgG and IgM antibody	PCL		**PCL COVID19 IgG/IgM Rapid Gold**[175] Qualitative detection of COVID-19 IgG/IgM antibodies using lateral flow technique	100%		Approved for inclusion on the Australian Register of Therapeutic Goods on 1 May 2020. [175]	10 minutes	(no info)
ELISA total antibodies	Bio-Rad Laboratories[334]		**ELISA Total Antibodies Platelia SARS-CoV-2 Total Antibody Assay**[384]	100% in Serum, 83.33% in Plasma	99.51% in Serum, 100% in Plasma	FDA EUA issued on 29/04/2020[384]	(no info)	(no info)

Serological tests (antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma EDTA					
Total Antibody Immunoassay	Wadsworth Center[385]		**New York SARS-CoV Microsphere Immunoassay for Antibody Detection** [386] Qualitative detection of total antibodies to SARS-CoV-2 in human serum.	88.0% (95/108)	99.6% (Blood donors), 98.7% (Diverse group of viral pathogens), 96.7% (Respiratory infections), 97.1% (Other study with respiratory infections)	FDA EUA issued on 30/04/2020 [386]	(no info)	(no info)
Total antibody Immunoassay	Roche Diagnostics		**Elecsys Anti-SARS-CoV-2**[387] Immunoassay for qualitative detection of antibodies to SARS-CoV-2	65.5% (76/116, Day 0-6 post-PCR confirmation); 88.1% (52/59, Day 7-13 post-PCR confirmation); 100% (29/29, >/= 14 days post-PCR confirmation)	99.81% (5262/5272)	FDA EUA issued on 2 May 2020[387]	(no info)	(no info)

RT-PCR: reverse transcription polymerase chain reaction

NGS: next generation sequencing

LAMP: loop-mediated isothermal amplification

CLIA: chemiluminescence immunoassay

ddPCR: digital droplet polymerase chain reaction

IgM: Immunoglobulin M

IgG: Immunoglobulin G

IgA: Immunoglobulin A

E: envelope gene

N: nucleocapsid protein gene

Nsp: non-structural protein gene

ORF: open reading frame gene

RdRp: RNA-dependent RNA polymerase gene

S: spike protein gene

RUO: Research Use Only

IVD: In Vitro Diagnostics

CDC: Centers for Disease Control and Prevention

CE Mark: Conformitè Europëenne (CE) Mark – European Union's mandatory conformity marking for regulating goods sold in European Economic Area

EUA: emergency use assessment

FDA: Food & Drug Administration (US)

NMPA: National Medical Products Administration (China)

ARTG: Australian Register of Therapeutic Goods (Australia)

HSA: Health Services Authority (Singapore)

rxn: reactions

Table 3. Approaches for Coronavirus Diagnostics

Type	Test	Coronavirus	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Duplex RT-PCR method with primers and probes targeting: pUC57SARS-pS2	SARS-CoV					
RT-PCR	Duplex RT-PCR method with primers and probes targeting: pGEM-MERSS2	MERS-CoV					
RT-PCR	Singleplex RT-iiPCR assays targeting open reading frame 1a gene: MERS-CoV ORF1a	MERS-CoV	99.3%	(no info)			
RT-PCR	Singleplex RT-iiPCR assays targeting envelope gene: upE RT-iiPCR	MERS-CoV	100%	(no info)			
rRT-PCR	AccuPower (Bioneer, Korea) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	Anyplex (Seegene, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	DiaPlexQ (SolGent, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	LightMix (Roche Molecular Diagnostics, Switzerland) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	UltraFast kits (Nanobiosys, Korea) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	PowerChek (Kogene Biotech, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	TaqMan probe-based one-step rRT-PCR assays for upE and ORF1b genes.	MERS-CoV					
rRT-PCR	Monoclonal antibodies-based rapid nucleoprotein assay	MERS-CoV	Detection limit of about 103.7-104.2 $TCID^{50}$/ml of MERS-CoV				
RT-LAMP	Two primer sets with one targeting the N gene and one targeting the ORF1a gene	MERS-CoV					
RT-LAMP-VF	Two primer sets with one targeting the N gene and one targeting the ORF1a gene combined with vertical flow visualization strip using nucleic acid visualization technique.	MERS-CoV		No cross-reactivity to multiple SARS-related-CoVs, including HKU1, HKU4, OC43 and 229E.			
(novel)	Arch-shaped multiple-target sensor	MERS-CoV				20 min	

RT-PCR: reverse transcription polymerase chain reaction

rRT-PCR: real-time reverse transcription polymerase chain reaction

RT-LAMP: reverse transcription loop-mediated isothermal amplification

RT-LAMP-VF: reverse transcription loop-mediated isothermal amplification with a vertical flow visualization strip

upE: envelope gene

ORF1a: open reading frame 1a

ORF1b: open reading frame 1b

Table 4. Gene Targets and Specimen Sample Types Tested with PCR

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
Ong et al (2020)[388]	RdRp E	81 min 15 sec	3 cases* Singapore	Surface environment, personal protective equipment, and air samples.
Chan et al (2020)[212]	RdRp S	200 min	6 cases Shenzhen, China	Nasopharyngeal and throat swabs, and stool and urine samples.
Huang C et al (2020)[389]	E	51 min 45 sec	41 cases Wuhan, China	Nasal and pharyngeal swabs, bronchoalveolar lavage fluid, sputum, or bronchial aspirates.
Phan et al (2020)[390]	(no info)	(no info)	2 cases Ho Chi Minh, Vietnam	Throat swab.
Chen Z et al (2020)[391]	E (same as Huang et al)	51 min 45 sec	99 cases Wuhan, China	Throat swab. (Plus sputum or endotracheal aspirates?)
Holshue et al (2020)[392]	N gene (Testing by US CDC)	(US CDC protocol)	1 case Snohomish County, USA	Nasopharyngeal and oropharyngeal swabs, stool and serum.
Lei et al (2020)[393]	(no info)	(no info)	1 case Lanzhou, China	Sputum.
Liu P et al (2020)[394]	(no info)	(no info)	1 case Hunan, China	Throat swab.
Chang et al (2020)[395]	(Testing by Beijing CDC)	(no info)	13 cases Beijing, China	Throat swabs.
Fang Y et al (2020a)[396]	(no info)	(no info)	2 cases Linhai, China	Sputum.
Liu K et al (2020)[397]	ORF1ab N (Biogerm test kit)	51 min 45 sec	137 cases 9 hospitals across Hubei province, China	Sputum and nasopharyngeal swab.
Shi et al (2020a)[70]	(no info)	(no info)	1 case Wuhan, China	Sputum.
Wang D et al (2020)[398]	ORF1ab N	60 min	138 cases Wuhan, China	Throat swab.
Liu Y et al (2020)[399]	ORF1ab N (GeneoDx test kit)	(Chinese CDC protocol)	12 cases Shenzhen, China	Throat swabs and bronchoalveolar lavage fluid.
Wang Z et al (2020)[400]	E (same as Huang et al)	51 min 45 sec	4 cases Shanghai, China	Throat swab.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
Bastola et al (2020)[401]	(Testing by WHO lab in Hong Kong)	(no info)	1 case Nepal	Throat swab.
Chen H et al (2020)[402]	ORF1ab N (Biogerm test kit)	51 min 45 sec	9 cases (pregnant women) Wuhan, China	Throat swab.
Duan et al (2020)[403]	(no info)	(no info)	1 case Guangzhou, China	Pharyngeal swab.
Huang P et al (2020)[404]	(no info)	(no info)	1 case Zhuhai, China	Sputum.
Li X et al (2020)[405]	(no info)	(no info)	1 case Hefei, China	Sputum.
Liu Y et al (2020)[406]	[cited Corman et al (2020) – assume E and RdRp genes]	(no info)	1 case Taiwan	Throat swab.
Liu T et al (2020)[407]	(no info)	(no info)	3 cases Zhuhai, China	Sputum.
Ng et al (2020)[408]	[cited Chan et al (2020) – assume RdRp and S genes]	200 min	21 cases [6 previously reported in Chan et al (2020)] Hong Kong and Shenzhen, China	Nose and throat swabs, and stool and urine samples.
Silverstein et al (2020)[409]	(no info)	(no info)	1 case Toronto, Canada	Mid-turbinate and throat swabs.
China CDC (2020)[410]	(no info)	(no info)	72,314 cases China	Throat swabs.
Wei M et al (2020)[411]	(no info)	(no info)	9 cases (infants under 1 yr) China	Nasopharyngeal swab.
Wu Y et al (2020)[412]	(no info)	(no info)	1 case Wuhan, China	Nasopharyngeal swab.
Van Cuong et al (2020)[413]	(sample ran by National Institute of Hygiene and Epidemiology)	(no info)	1 case Hanoi, Vietnam	Nasopharyngeal swab.
Xu Z et al (2020)[414]	(Testing by Beijing CDC)	(no info)	1 case Beijing, China	Throat swab.
Fang Y et al (2020b)[415]	(Shanghai ZJ Bio-Tech test kit)	(no info)	51 cases	Throat swab or sputum sample.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
			Taizhou, China	
Huang W et al (2020) [416]	(Testing by Taiwan CDC)	(no info)	2 cases Taichung, Taiwan	Nasopharyngeal swab.
Zou et al (2020)[417]	N ORF1b	(no info)	18 cases Zhuhai, China	Nasal and throat swabs.
Xu X et al (2020a)[418]	(no info)	(no info)	62 cases 7 hospitals in Zhejiang province, China	Throat swabs and sputum samples.
Bernheim et al (2020)[68]	(Test kits by Sansure Biotech, Shanghai Zhijiang Biotechnology, or Da An Gene)	(no info)	121 cases China	Nasopharyngeal or oropharyngeal swab, bronchoalveolar lavage fluid, or endotracheal aspirate.
Zhu N et al (2020)[419]	RdRp	41 min 50 sec	3 cases Wuhan, China	Bronchoalveolar lavage fluid.
Pan et al (2020)[420]	(no info)	(no info)	2 cases Beijing, China	Throat swabs, sputum, urine, and stool samples.
Shi et al (2020b)[70]	E	(no info)	81 cases Wuhan, China	Throat swabs.
Wei J et al (2020)[421]	(no info)	(no info)	1 case Nanchang, China	Sputum.
Yang W et al (2020)[422]	(no info)	(no info)	149 cases Wenzhou, China	Nasal and pharyngeal swabs, sputum.
Lan et al (2020)[423]	ORF1ab N (Biogerm test kit) [cited Wang D et al (2020)]	60 min [cited Wang D et al (2020)]	4 cases Wuhan, China	Throat swabs.
Cai et al (2020)[424]	ORF1ab N	(no info)	10 cases (children) China	Nasopharyngeal and throat swabs, urine and serum samples.
Guan at al (2020)[425]	(no info)	(no info)	1099 cases China	Nasal and pharyngeal swabs.
Kam et al (2020)[426]	N ORF1ab	89 min 10 sec 72 min 30 sec	1 case Singapore	Nasopharyngeal swabs, blood, stool, and urine samples.
Lillie et al (2020)[427]	(no info)	(no info)	2 cases UK	Nasopharyngeal, nose and throat swabs.
Ling et al (2020)[428]	(no info)	(no info)	66 cases	Oropharyngeal swabs or stool samples.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
			Shanghai, China	
Tian et al (2020)[429]	(no info)	(no info)	2 cases Wuhan, China	Pharyngeal swab.
Li K et al (2020)[430]	(no info)	(no info)	83 cases Chongqing and Jinan, China	Throat swabs or lower respiratory tract samples.
Wu J et al (2020)[431]	N ORF1ab (Biogerm test kit)	48 min 20 sec	80 cases 3 hospitals across Jiangsu province, China	Nose and/or throat swabs.
Xiong et al (2020)[432]	(no info)	(no info)	42 cases Wuhan, China	Nasopharyngeal or oropharyngeal swabs.
Young et al (2020)[433]	N ORF1ab S	89 min 10 sec 72 min 30 sec 72 min 30 sec	18 cases Singapore	Nasopharyngeal swabs, blood, stool, and urine samples.
Zhu et al (2020)[434]	(no info)	(no info)	6 cases Guangzhou, China	Oropharyngeal swabs.
Fan et al (2020)[435]	(Testing by NCID)	(no info)	69 cases Singapore	Respiratory samples.
Hu et al (2020)[436]	(Test kit by BGI Genomics)	(no info)	24 cases Nanjing, China	Pharyngeal swabs.
Li Y et al (2020) [437]	(no info)	(no info)	51 cases Wuhan, China	Oropharyngeal swabs.
Yan et al (2020)[438]	N ORF1ab	(no info)	2 cases Singapore	Nasopharyngeal swabs.
Liu Y et al (2020)[439]	(no info)	(no info)	18 cases (pregnant women) China	Oropharyngeal swabs.
Wang et al (2020)[440]	(Testing by Henan CDC)	(no info)	18 cases Zhengzhou, China	Throat swabs.
Xia et al (2020)[441]	(no info)	(no info)	20 cases (children) Wuhan, China	Pharyngeal swabs.
Zhou et al (2020)[442]	(no info)	(no info)	62 cases Wuhan, China	Respiratory samples.

E: envelope gene

N: nucleocapsid protein gene

ORF: open reading frame gene

RdRp: RNA-dependent RNA polymerase gene

S: spike protein gene

References

1. Corman VM et al (2020) Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. *Euro Surveill.*(28 Jan 2020). Available at:
2. Medical Technology (2020) The Importance of Diagnostic Tests in Fighting Infectious Diseases 2020. Available at: https://www.lifechanginginnovation.org/medtech-facts/importance-diagnostic-tests-fighting-infectious-diseases (accessed 28 Jan 2020)
3. FIND (2020) SARS-CoV-2 Diagnostic Pipeline. Available at: https://www.finddx.org/covid-19/pipeline/ (accessed 26 Mar 2020)
4. Sheridan C (2020) Coronavirus and the race to distribute reliable diagnostics. Nature. 21 Feb 2020. Available at: https://www.nature.com/articles/d41587-020-00002-2 (accessed 26 Feb 2020)
5. Sheridan C (2020) Fast, portable tests come online to curb coronavirus pandemic. Nature. 23 Mar 2020. Available at: https://www.nature.com/articles/d41587-020-00010-2 (accessed 26 Mar 2020)
6. 360Dx (2020) Coronavirus Test Tracker: Commercially Available COVID-19 Diagnostic Tests. 24 Mar 2020. Available at: https://www.360dx.com/coronavirus-test-tracker-launched-covid-19-tests (accessed 26 Mar 2020)
7. Zhang N et al (2020) Recent advances in the detection of respiratory virus infection in humans. *J Med Virol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/31944312
8. World Health Organization (2020) Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases - Interim Guidance 2020. 17 Jan 2020. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance. (accessed 28 Jan 2020)
9. World Health Organization (2020) Novel Coronavirus (2019-nCoV) technical guidance: Laboratory testing for 2019-nCoV in humans. 31 Jan 2020. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance (accessed 31 Jan 2020)
10. Institut Pasteur (2020) Protocol: Real-time RT-PCR assays for the detection of SARS-CoV-2. 02 Mar 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/real-time-rt-pcr-assays-for-the-detection-of-sars-cov-2-institut-pasteur-paris.pdf?sfvrsn=3662fcb6_2 (accessed 09 Mar 2020)
11. Liu D et al (2020) China Applies Stricter Criteria for Diagnosing Covid-19 Cases. Caixin. 20 Feb 2020. Available at: https://www.caixinglobal.com/2020-02-20/china-applies-stricter-criteria-for-diagnosing-covid-19-cases-101517843.html (accessed 20 Feb 2020)
12. Charité Virology (2020) Diagnostic detection of Wuhan coronavirus 2019 (17 Jan 2019). 17 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2 (accessed 28 Jan 2020)
13. School of Public Health The University of Hong Kong (2020) Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR. 16 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/peiris-protocol-16-1-20.pdf?sfvrsn=af1aac73_4 (accessed 28 Jan 2020)
14. Chu DKW et al (2020) Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia. *Clin Chem.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32031583
15. US Department of Health & Human Services (2020) Real-Time RT-PCR Panel for Detection 2019-Novel Coronavirus. 24 Jan 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-for-detection-instructions.pdf (accessed 28 Jan 2020)
16. US Department of Health & Human Services (2020) 2019-Novel Coronavirus (2019-nCoV) Real-time rRT-PCR Panel Primers and Probes. 24 Jan 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-primer-probes.pdf (accessed 28 Jan 2020)
17. US Department of Health & Human Services (2020) CDC Tests for 2019-nCoV. 05 Feb 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html (accessed 10 Feb 2020)
18. Johnson M (2020) Coronavirus Test Kits Encounter QC Hiccup in Some States, CDC Reports. GenomeWeb. 12 Feb 2020 Available at: https://www.genomeweb.com/pcr/coronavirus-test-kits-encounter-qc-hiccup-some-states-cdc-reports#.XkTV2VIzYcg (accessed 13 Feb 2020)

19. Feuer W (2020) Amid testing capacity concerns, CDC unveils new coronavirus test kits. CNBC. 28 Feb 2020. Available at: https://www.cnbc.com/2020/02/28/amid-testing-capacity-concerns-cdc-unveils-new-coronavirus-test-kits.html (accessed 03 Mar 2020)
20. Chuck E (2020) After missteps, CDC says its coronavirus test kit is ready for primetime. CNBC. 29 Feb 2020. Available at: https://www.nbcnews.com/health/health-news/after-missteps-cdc-says-its-coronavirus-test-kit-ready-primetime-n1145206 (accessed 03 Mar 2020)
21. Lim D et al (2020) U.S. health officials probe coronavirus test problems at CDC. Politico. Available at: https://www.politico.com/news/2020/03/01/health-officials-probe-coronavirus-cdc-118523 (accessed 03 Mar 2020)
22. Swan J et al (2020) Scoop: CDC lab for coronavirus test kits may have been contaminated. Axios. 01 Mar 2020. Available at: https://www.axios.com/cdc-lab-coronavirus-contaminated-6dc9726d-dea3-423f-b5ad-eb7b1e44c2e2.html (accessed 02 Mar 2020)
23. US Food and Drug Administration (2020) Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics. 29 Feb 2020. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics (accessed 03 Mar 2020)
24. Integrated DNA Technologies (2020) 2019 Novel Coronavirus (2019-nCoV). Available at: https://www.idtdna.com/pages/landing/coronavirus-research-reagents (accessed 11 Mar 2020)
25. LGC (2020) LGC, Biosearch Technologies detection reagents approved by CDC for COVID-19 diagnosis. 09 Mar 2020. Available at: https://www.lgcgroup.com/newsroom-and-blog/news-and-blog/detection-reagents-approved-by-cdc/ (accessed 17 Mar 2020)
26. CNBC (2020) FDA grants 'emergency use' coronavirus test that can deliver results in 45 minutes. 21 Mar 2020. Available at: https://www.cnbc.com/2020/03/21/fda-grants-emergency-use-coronavirus-test-that-can-deliver-results-in-45-minutes.html (accessed 23 Mar 2020)
27. US Food and Drug Administration (2020) Abbott RealTime SARS-CoV-2 Assay (Abbott Molecular) - Letter of Authorization. 18 Mar 2020. Available at: https://www.fda.gov/media/136255/download (accessed 23 Mar 2020)
28. US Food and Drug Administration (2020) PerkinElmer New Coronavirus Nucleic Acid Detection Kit - Latter of Authorization. 24 Mar 2020. Available at: https://www.fda.gov/media/136407/download (accessed 26 Mar 2020)
29. US Food and Drug Administration (2020) ID NOW COVID-19 (Abbott Diagnostics). 27 Mar 2020. Available at: https://www.fda.gov/media/136522/download (accessed 31 Mar 2020)
30. PR Newswire (2020) Mesa Biotech Receives Emergency Use Authorization from FDA for a 30 Minute Point of Care Molecular COVID-19 Test. 24 Mar 2020. Available at: https://www.prnewswire.com/news-releases/mesa-biotech-receives-emergency-use-authorization-from-fda-for-a-30-minute-point-of-care-molecular-covid-19-test-301028687.html (accessed 26 Mar 2020)
31. Cortez MF (2020) Abbott Launches 5-Minute Virus Test for Use Almost Anywhere. Bloomberg. 28 Mar 2020. Available at: https://www.bloomberg.com/news/articles/2020-03-27/abbott-launches-5-minute-covid-19-test-for-use-almost-anywhere (accessed 03 Apr 2020)
32. Hyde E (2020) The CRISPR Platform for Next-Generation Therapeutics and Diagnostics. Synbiobeta. 30 Jan 2020. Available at: https://synbiobeta.com/the-crispr-platform-for-next-generation-therapeutics-and-diagnostics/ (accessed 05 Feb 2020)
33. Rosenbaum L (2020) Mammoth Biosciences Raises $45 Million For Crispr Diagnostics—And Its Tech Is Already Being Used Against Coronavirus. Forbes. 30 Jan 2020. Available at: https://www.forbes.com/sites/leahrosenbaum/2020/01/30/mammoth-biosciences-raises-45-million-to-create-crispr-diagnostic-tests-and-its-tech-is-already-being-used-against-coronavirus/#8faec3f56c91 (accessed 05 Feb 2020)
34. Molteni M (2020) The US Fast-Tracked a Coronavirus Test to Speed Up Diagnoses. WIRED. 04 Feb 2020. Available at: https://www.wired.com/story/the-us-fast-tracked-a-coronavirus-test/ (accessed 05 Feb 2020)
35. Broughton JP et al (2020) CRISPR–Cas12-based detection of SARS-CoV-2. *Nature Biotechnology*. Available at: https://doi.org/10.1038/s41587-020-0513-4
36. Alekseyev YO et al (2018) A next-generation sequencing primer—how does it work and what can it do? *Academic pathology*.5:2374289518766521. Available at:
37. Fulgent (2020) Coronavirus Testing Available at: https://www.fulgentgenetics.com/covid19 (accessed 22 April)

38. Thevarajan I et al (2020) Breadth of concomitant immune responses prior to patient recovery: a case report of non-severe COVID-19. *Nature Medicine.* Available at: https://doi.org/10.1038/s41591-020-0819-2
39. Channel News Asia (2020) Duke-NUS used COVID-19 antibody tests to establish link between church clusters in a world-first. 26 Feb 2020. Available at: https://www.channelnewsasia.com/news/singapore/covid19-coronavirus-duke-nus-antibody-tests-12469184 (accessed 26 Feb 2020)
40. Chew E (2020) Singapore Researchers Make Advances in Coronavirus Test Method. Bloomberg. 26 Feb 2020. Available at: https://www.bloomberg.com/news/articles/2020-02-26/singapore-researchers-make-breakthrough-in-coronavirus-testing (accessed 26 Feb 2020)
41. Cao Q (2020) China develops COVID-19 detection kit that delivers results in 15 minutes. CGTN. CGTN. 15 Feb 2020. Available at: https://news.cgtn.com/news/2020-02-15/China-develops-COVID-19-detection-kit-that-delivers-results-in-15-min--O6aPGKuzGo/index.html (accessed 20 Feb 2020)
42. Global Times (2020) New COVID-19 drugs approved for fast and accurate diagnosis: China's top epidemiologist. 23 Feb 2020. Available at: http://www.globaltimes.cn/content/1180544.shtml (accessed 26 Feb 2020)
43. Gao Y (2020) China greenlights new testing kits to identify COVID-19. CGTN. 24 Feb 2020. Available at: https://news.cgtn.com/news/2020-02-24/China-greenlights-new-testing-kits-to-identify-COVID-19-Ol9QqDDWRa/index.html (accessed 26 Feb 2020)
44. GBI Source (2020) Wondfo Bio's 2 coronavirus detection kits super fast-track in China. 20 Feb 2020. Available at: https://source.gbihealth.com/News/NewsDetail?newsID=2033702&newsType=news (accessed 26 Feb 2020)
45. Qiu Q (2020) China greenlights new coronavirus detection method. 23 Feb 2020. Available at: https://www.chinadaily.com.cn/a/202002/23/WS5e528b42a3101282172799b6.html (accessed 26 Feb 2020)
46. Guangzhou Wondfo Biotech (2020) Guangzhou Wondfo Biotech's New Coronavirus Test Products Receive CE Mark. 06 Mar 2020. Available at: http://www.szse.cn/disclosure/listed/bulletinDetail/index.html?445b33ef-b062-46f0-9a1a-0801d94c1dc9 (accessed 12 Mar 2020)
47. Reuters (2020) Guangzhou Wondfo Biotech's Three New Coronavirus Test Products Receive CE Mark, Qualified To Enter EU Market. 06 Mar 2020. Available at: https://www.reuters.com/article/brief-guangzhou-wondfo-biotechs-three-ne/brief-guangzhou-wondfo-biotechs-three-new-coronavirus-test-products-receive-ce-mark-qualified-to-enter-eu-market-idUSL4N2AZ2WK (accessed 12 Mar 2020)
48. PR Newswire (2020) German Company Pharmact AG Develops a Point-of-Care Rapid Test for the Detection of the Coronavirus (SARS-CoV-2). 10 Mar 2020. Available at: https://www.prnewswire.com/news-releases/german-company-pharmact-ag-develops-a-point-of-care-rapid-test-for-the-detection-of-the-coronavirus-sars-cov-2-301020339.html (accessed 11 Mar 2020)
49. 360Dx (2020) Aytu BioScience Licenses US Rights to Point-of-Care Coronavirus Test. 10 Mar 2020. Available at: https://www.360dx.com/infectious-disease/aytu-bioscience-licenses-us-rights-point-care-coronavirus-test#.XmhTLKgzaUk (accessed 11 Mar 2020)
50. Accesswire (2020) Aytu BioScience Secures Exclusive U.S. Distribution Agreement for Coronavirus 2019 (COVID-19) Point-of-Care Rapid Test. 10 Mar 2020. Available at: https://www.accesswire.com/579898/Aytu-BioScience-Secures-Exclusive-US-Distribution-Agreement-for-Coronavirus-2019-COVID-19-Point-of-Care-Rapid-Test (accessed 11 Mar 2020)
51. SD Biosensor (2020) STANDARD Q COVID-19 IgM IgG Duo. Available at: http://sdbiosensor.com/xe/product/7662 (accessed 12 Mar 2020)
52. Xinhua (2020) Chinese researchers develop rapid antibody test kit for coronavirus. 21 Feb 2020. Available at: http://www.xinhuanet.com/english/2020-02/21/c_138805748.htm (accessed 09 Mar 2020)
53. China Plus (2020) Researchers develop quick test for novel coronavirus. 12 Feb 2020. Available at: http://chinaplus.cri.cn/recommended/1661/419776 (accessed 20 Feb 2020)
54. Xinhua (2020) Chinese university develops rapid test kit for novel coronavirus 17 Feb 2020. Available at: www.xinhuanet.com/english/2020-02/17/c_138791386.htm (accessed 18 Feb 2020)

55. Li Z et al (2020) Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis. *J Med Virol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32104917
56. BioMedomics (2020) BioMedomics Receives CE-IVD Certification for its New COVID-19 IgM-IgG Rapid Test for Novel Coronavirus. 08 Mar 2020. Available at: https://www.hospimedica.com/coronavirus/articles/294781129/biomedomics-launches-covid-19-igm-igg-rapid-test-for-novel-coronavirus.html (accessed 17 Mar 2020)
57. Scudellari M (2020) Wanted: Rapid, Portable Tests for Coronavirus IEEE Spectrum. 13 Mar 2020. Available at: https://spectrum.ieee.org/the-human-os/biomedical/diagnostics/rapid-portable-tests-coronavirus-news (accessed 17 Mar 2020)
58. Teater B (2020) RTP-based BioMedomics seeks FDA OK for 'emergency use' of its coronavirus test WRAL TechWire. 13 Mar 2020. Available at: https://www.wraltechwire.com/2020/03/13/rtp-based-biomedomics-seeks-fda-ok-for-coronavirus-test-to-meet-backlog/ (accessed 17 Mar 2020)
59. Cellex (2020) Cellex qSARS-CoV-2 IgG/IgM Rapid Test. 01 Apr 2020. Available at: https://www.fda.gov/media/136625/download (accessed 02 Apr 2020)
60. FIND (2020) FIND Evaluation Update: SARS-CoV-2 Immunoassays. Available at: https://www.finddx.org/covid-19/sarscov2-eval-immuno/ (accessed 09 Apr 2020)
61. 360Dx (2020) Iceni Diagnostics Developing Point-of-Care, Lateral flow Assay for SARS-CoV-2. 2020. Available at: https://www.360dx.com/point-care-testing/iceni-diagnostics-developing-point-care-lateral-flow-assay-sars-cov-2#.XpwFQ8gzZEY
62. Koczula Katarzyna M et al (2016) Lateral flow assays. *Essays in Biochemistry.*60(1):111-120. Available at: https://doi.org/10.1042/EBC20150012 (accessed 4/27/2020)
63. Bagdonaite I et al (2018) Global aspects of viral glycosylation. *Glycobiology.*28(7):443-467. Available at: https://doi.org/10.1093/glycob/cwy021 (accessed 4/27/2020)
64. Academia Sinica (2020) Catching Virus Fast! Academia Sinica discovered useful antibodies for developing rapid immune based test kit of SARS-CoV-2 coronavirus. 09 Mar 2020. Available at: https://www.sinica.edu.tw/en/news/6505 (accessed 30 Mar 2020)
65. Parra A et al (2020) Virus test results in minutes? Scientists question accuracy. ABC News. 27 Mar 2020. Available at: https://abcnews.go.com/Business/wireStory/virus-test-results-minutes-scientists-question-accuracy-69834536 (accessed 30 Mar 2020)
66. Patton D et al (2020) China's Hubei province sees surge in coronavirus deaths on switch to new methodology. Reuters. Available at:
67. Chung M et al (2020) CT Imaging Features of 2019 Novel Coronavirus (2019-nCoV). *Radiology.*200230. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32017661
68. Bernheim A et al (2020) Chest CT Findings in Coronavirus Disease-19 (COVID-19): Relationship to Duration of Infection. *Radiology.*200463. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32077789
69. Ai T et al (2020) Correlation of Chest CT and RT-PCR Testing in Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases. *Radiology.*200642. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32101510
70. Shi H et al (2020) Radiological findings from 81 patients with COVID-19 pneumonia in Wuhan, China: a descriptive study. *Lancet Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32105637
71. Xie X et al (2020) Chest CT for Typical 2019-nCoV Pneumonia: Relationship to Negative RT-PCR Testing. *Radiology.*200343. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32049601
72. Sun H (2020) Alibaba says AI can identify coronavirus infections with 96% accuracy Nikkei Asian Review. 19 Feb 2020. Available at: https://asia.nikkei.com/Spotlight/Coronavirus/Alibaba-says-AI-can-identify-coronavirus-infections-with-96-accuracy (accessed 20 Feb 2020)
73. Khalid A (2020) Why a wave of at-home coronavirus tests is dividing global regulators. Quartz. 26 Mar 2020. Available at: https://qz.com/1825423/why-global-regulators-are-divided-over-new-coronavirus-tests/ (accessed 26 Mar 2020)
74. Loh T et al (2020) U.K. Says 3.5 Million Tests For Virus Exposure Will Be Available Within Days. Bloomberg. 26 Mar 2020. Available at: https://www.bloomberg.com/news/articles/2020-03-25/u-k-says-3-5-million-tests-that-show-virus-exposure-coming-soon (accessed 26 Mar 2020)
75. Johnson M (2020) In Coronavirus Assay Validation for Emergency Use, Labs Encounter Multiple Pain Points. 11 Mar 2020. Available at:

https://www.genomeweb.com/pcr/coronavirus-assay-validation-emergency-use-labs-encounter-multiple-pain-points#.XnHCD9MzbBL (accessed 26 Mar 2020)
76. Public Health England (2020) COVID-19: rapid tests for use in community pharmacies or at home. 15 Mar 2020. Available at: https://www.gov.uk/government/publications/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home (accessed 26 Mar 2020)
77. Schraer R (2020) Coronavirus: Home tests won't be available 'next week'. BBC News. 25 Mar 2020. Available at: https://www.bbc.com/news/health-52035615 (accessed 26 Mar 2020)
78. McGowan M et al (2020) Rapid Covid-19 testing kits receive urgent approval from Australian regulator. The Guardian. 23 Mar 2020. Available at: https://www.theguardian.com/australia-news/2020/mar/24/rapid-covid-19-testing-kits-receive-urgent-approval-from-australian-regulator (accessed 26 Mar 2020)
79. Australian Government Department of Health (2020) COVID-19 diagnostic tests included on the ARTG for legal supply in Australia. 02 Apr 2020. Available at: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia (accessed 02 Apr 2020)
80. Kim C et al (2011) Comparison of nasopharyngeal and oropharyngeal swabs for the diagnosis of eight respiratory viruses by real-time reverse transcription-PCR assays. *PLoS One.*6(6):e21610. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21738731
81. Kelly-Cirino C et al (2019) An updated roadmap for MERS-CoV research and product development: focus on diagnostics. *BMJ Glob Health.*4(Suppl 2):e001105. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30815285
82. Public Health Laboratory Network (2020) PHLN guidance on laboratory testing for 2019-nCoV 2020. Jan 2020. Available at: https://www.health.gov.au/sites/default/files/documents/2020/01/phln-guidance-on-laboratory-testing-for-2019-ncov-phln-guidance-on-laboratory-testing-for-novel-coronavirus-2019-ncov.pdf (accessed 28 Jan 2020)
83. US Department of Health & Human Services (2020) Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19). 14 Feb 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html (accessed 18 Feb 2020)
84. Jin YH et al (2020) A rapid advice guideline for the diagnosis and treatment of 2019 novel coronavirus (2019-nCoV) infected pneumonia (standard version). *Mil Med Res.*7(1):4. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32029004
85. Yang Y et al (2020) Laboratory diagnosis and monitoring the viral shedding of 2019-nCoV infections. *medRxiv.* Available at: https://www.medrxiv.org/content/10.1101/2020.02.11.20021493v2
86. To KK et al (2020) Consistent detection of 2019 novel coronavirus in saliva. *Clin Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32047895
87. Tu Y-P et al (2020) Patient-collected tongue, nasal, and mid-turbinate swabs for SARS-CoV-2 yield equivalent sensitivity to health care worker collected nasopharyngeal swabs. *medRxiv.*2020.2004.2001.20050005. Available at: https://www.medrxiv.org/content/medrxiv/early/2020/04/06/2020.04.01.20050005.full.pdf
88. Kojima N et al (2020) Self-Collected Oral Fluid and Nasal Swabs Demonstrate Comparable Sensitivity to Clinician Collected Nasopharyngeal Swabs for Covid-19 Detection. *medRxiv.*2020.2004.2011.20062372. Available at: https://www.medrxiv.org/content/medrxiv/early/2020/04/15/2020.04.11.20062372.full.pdf
89. Ting V (2020) Coronavirus: Hong Kong's private clinics set to launch Covid-19 testing, but infection risks, potential stigma has many in sector wary. South China Morning Post. 09 Mar 2020. Available at: https://www.scmp.com/news/hong-kong/health-environment/article/3074315/coronavirus-hong-kongs-private-clinics-now-able (accessed 17 Mar 2020)
90. Business Wire (2020) Genomics Company Lucence Develops Viral Sample Collection Medical Device for COVID-19 Diagnosis and Surveillance. 20 Mar 2020. Available at: https://www.businesswire.com/news/home/20200320005151/en/Genomics-Company-Lucence-Develops-Viral-Sample-Collection (accessed 23 Mar 2020)
91. Rutgers (2020) New Rutgers Saliva Test for Coronavirus Gets FDA Approval. 13 Apr 2020. Available at: https://www.rutgers.edu/news/new-rutgers-saliva-test-coronavirus-gets-fda-approval (accessed 17 Apr 2020)

92. US Food and Drug Administration (2020) Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay EUA Summary. 10 Apr 2020. Available at: https://www.fda.gov/media/136875/download (accessed 17 Apr 2020)
93. FDA (2020) Coronavirus (COVID-19) Update: FDA, Gates Foundation, UnitedHealth Group, Quantigen, and U.S. Cotton Collaborate to Address Testing Supply Needs. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-gates-foundation-unitedhealth-group-quantigen-and-us-cotton (accessed 22 April)
94. Tang Y-W et al (2020) The laboratory diagnosis of COVID-19 infection: current issues and challenges. *Journal of Clinical Microbiology.* Available at:
95. Hope MD et al (2020) A role for CT in COVID-19? What data really tell us so far. *The Lancet*.395(10231):1189-1190. Available at: https://doi.org/10.1016/S0140-6736(20)30728-5 (accessed 2020/04/22)
96. Charité Virology (2020) Diagnostic detection of Wuhan coronavirus 2019 (13 Jan 2019). 13 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf?sfvrsn=d381fc88_2 (accessed 28 Jan 2020)
97. Chinese Center for Disease Control and Prevention (2020) Specific primers and probes for detection 2019 novel coronavirus. 21 Jan 2020. Available at: http://ivdc.chinacdc.cn/kyjz/202001/t20200121_211337.html (accessed 28 Jan 2020)
98. Department of Medical Sciences Ministry of Public Health Thailand (2020) Conventional RT-PCR for Detection of nCoV. Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/conventional-rt-pcr-followed-by-sequencing-for-detection-of-ncov-rirl-nat-inst-health-t.pdf (accessed 28 Jan 2020)
99. Nao N et al (2020) Detection of second case of 2019-nCoV infection in Japan (corrected version). 23 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/method-niid-20200123-2.pdf?sfvrsn=fbf75320_7 (accessed 28 Jan 2020)
100. Today (2020) BRIEF-Jiangsu Bioperfectus Technologies Develops Test Kit For New China Coronavirus. 14 Jan 2020. Available at: https://www.todayonline.com/world/brief-jiangsu-bioperfectus-technologies-develops-test-kit-new-china-coronavirus (accessed 30 Jan 2020)
101. Oxford Nanopore Technologies (2020) Novel Coronavirus (nCoV-2019). 22 Jan 2020. Available at: https://nanoporetech.com/about-us/news/novel-coronavirus-ncov-2019 (accessed 31 Jan 2020)
102. Johnson M (2020) Diagnostics Developers Leap Into Action on Novel Coronavirus Tests. GenomeWeb. Available at: https://www.genomeweb.com/pcr/diagnostics-developers-leap-action-novel-coronavirus-tests#.XjObEmgzaUk (accessed 30 Jan 2020)
103. Nanopore (2020) News from the customer community. 6 March 2020. Available at: https://nanoporetech.com/about-us/news/covid19-community (accessed 22 April)
104. Artic Network (2020) About: The Project. Available at: https://artic.network/about.html (accessed 31 Jan 2020)
105. Artic Network (2020) nCoV-2019. Available at: https://artic.network/ncov-2019
106. Co-Diagnostics Inc (2020) Co-Diagnostics Inc Designs Test for New Coronavirus Using CoPrimer Platform. 23 Jan 2020. Available at: http://codiagnostics.com/co-diagnostics-designs-new-coronavirus-test-using-coprimers/ (accessed 30 Jan 2020)
107. Co-Diagnostics Inc (2020) Co-Diagnostics, Inc. Announces Sales of New Coronavirus Test. 10 Feb 2020. Available at: http://codiagnostics.com/co-diagnostics-announces-sales-of-new-coronavirus-test/ (accessed 11 Feb 2020)
108. US Food and Drug Administration (2020) Logix Smart Coronavirus Disease 2019 (COVID-19) kit (Co-Diagnostics) - Letter of Authorization. 03 Apr 2020. Available at: https://www.fda.gov/media/136684/download (accessed 08 Apr 2020)
109. FDA (2020) Logix Smart™ Coronavirus Disease 2019 (COVID-19) Kit. Available at: fda.gov/media/136687/download (accessed 23 April)
110. Genetic Engineering & Biotechnology News (2020) Coronavirus Detection Test in the Works for Wuhan. 24 Jan 2020. Available at: https://www.genengnews.com/news/coronavirus-detection-test-in-the-works-for-wuhan/ (accessed 30 Jan 2020)
111. GenomeWeb (2020) Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark. 24 Feb 2020. Available at: https://www.genomeweb.com/pcr/co-diagnostics-sars-cov-2-assay-garners-ce-mark#.XlXUcSgzaUk (accessed 26 Feb 2020)
112. altona Diagnostics (2020) altona Diagnostics is developing a RT-PCR kit for detection of novel coronavirus (2019-nCoV). 23 Jan 2020. Available at: https://altona-

diagnostics.com/en/news/assay-for-novel-coronavirus-under-development.html (accessed 28 Jan 2020)
113. Konrad R et al (2020) Rapid establishment of laboratory diagnostics for the novel coronavirus SARS-CoV-2 in Bavaria, Germany, February 2020. *Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin.*25(9):2000173. Available at: https://pubmed.ncbi.nlm.nih.gov/32156330 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7068163/
114. BGI (2020) BGI Develops Real-Time Fluorescent RT-PCR kit for detecting the 2019 Novel Coronavirus. 23 Jan 2020. Available at: https://www.bgi.com/global/company/news/bgi-develops-real-time-dna-based-kit-for-detecting-the-2019-novel-coronavirus/ (accessed 30 Jan 2020)
115. BGI (2020) BGI's Real-Time SARS-CoV-2 Test to Detect Novel Coronavirus Receives FDA Emergency Use Authorization. 27 Mar 2020. Available at: https://www.bgi.com/us/company/news/bgis-real-time-sars-cov-2-test-to-detect-novel-coronavirus-receives-fda-emergency-use-authorization/ (accessed 31 Mar 2020)
116. US Food and Drug Administration (2020) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI) - Letter of Authorization. Available at: https://www.fda.gov/media/136473/download
117. BGI (2020) BGI RT-PCR Kit and PMseq® Solution for Detecting 2019-nCoV. Available at: (accessed 30 Jan 2020)
118. FDA (2020) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV. Available at: fda.gov/media/136472d/download (accessed 22 April)
119. BGI (2020) BGI Receives CE Mark for Novel Coronavirus Test. 02 Mar 2020. Available at: https://www.bgi.com/global/company/news/bgi-receives-ce-mark-for-novel-coronavirus-test/ (accessed 09 Mar 2020)
120. BGI (2020) Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV. Available at: https://www.bgi.com/global/molecular-genetics/2019-ncov-detection-kit/ (accessed 30 Jan 2020)
121. Veredus Laboratories Pte Ltd (2020) Veredus Laboratories Announces the Development of a Lab-on-Chip for the detection of 3 coronaviruses: MERS-CoV, SARS-CoV and 2019-nCoV. 24 Jan 2020. Available at: http://vereduslabs.com/wordpress/wp-content/uploads/2020/01/VereCoV-Press-Release-Final.pdf (accessed 30 Jan 2020)
122. Koh D (2020) iHealthtech researchers working on Wuhan novel coronavirus (2019-nCoV) detection kit. 06 Feb 2020. Available at: https://www.mobihealthnews.com/news/asia-pacific/ihealthtech-researchers-working-wuhan-novel-coronavirus-2019-ncov-detection-kit (accessed 06 Mar 2020)
123. Koh D (2020) Veredus Laboratories' VereCoV detection kit obtains provisional approval for IVD use. MobiHealthNews. 03 Mar 2020. Available at: https://www.mobihealthnews.com/news/asia-pacific/veredus-laboratories-verecov-detection-kit-obtains-provisional-approval-ivd-use (accessed 06 Mar 2020)
124. Yang G (2020) WUHAN VIRUS TEST KIT DEVELOPED BY A SINGAPORE FIRM IS EXPECTED TO BE OUT BY 1 FEB 2020. Goody Feed. Available at: https://goodyfeed.com/wuhan-virus-test-kit/ (accessed 30 Jan 2020)
125. Mohan M (2020) New COVID-19 test kits used to screen swab samples collected at Singapore checkpoints. Channel News Asia. 06 Mar 2020. Available at: https://www.channelnewsasia.com/news/singapore/covid19-new-test-kits-swab-three-hours-12505658 (accessed 11 Mar 2020)
126. Ng RJ (2020) Singapore biotech firm Veredus expects to have Wuhan virus test by Feb 1. The Business Times. 25 Jan 2020. Available at: https://www.businesstimes.com.sg/companies-markets/singapore-biotech-firm-veredus-expects-to-have-wuhan-virus-test-by-feb-1 (accessed 30 Jan 2020)
127. Begley S (2020) DNA sleuths read the coronavirus genome, tracing its origins. STAT. 24 Jan 2020. Available at: https://www.statnews.com/2020/01/24/dna-sleuths-read-coronavirus-genome-tracing-origins-and-mutations/ (accessed 06 Feb 2020)
128. Johnson M (2020) Diagnostics Firms Rush to Develop Rapid Point-of-Care Tests for Novel Coronavirus. 360Dx. 12 Feb 2020. Available at: https://www.360dx.com/pcr/diagnostics-firms-rush-develop-rapid-point-care-tests-novel-coronavirus#.Xmsy5KgzaUk (accessed 02 Mar 2020)
129. Cepheid (2020) Cepheid and Sherlock Biosciences Establish Collaboration on New GeneXpert Tests for Infectious Diseases and Oncology Leveraging CRISPR Technology. 28

Feb 2020. Available at: http://cepheid.mediaroom.com/2020-02-28-Cepheid-and-Sherlock-Biosciences-Establish-Collaboration-on-New-GeneXpert-Tests-for-Infectious-Diseases-and-Oncology-Leveraging-CRISPR-Technology (accessed 02 Mar 2020)
130. MIT McGovern Institute (2020) Enabling coronavirus detection using CRISPR-Cas13_ An open-access SHERLOCK research protocol. 14 Feb 2020. Available at: https://mcgovern.mit.edu/2020/02/14/enabling-coronavirus-detection-using-crispr-cas13-an-open-access-sherlock-research-protocol/ (accessed 02 Mar 2020)
131. Zhang F et al (2020) A protocol for detection of COVID-19 using CRISPR diagnostics (v.20200214). 14 Feb 2020. Available at: https://www.broadinstitute.org/files/publications/special/COVID-19%20detection%20(updated).pdf (accessed 18 Feb 2020)
132. US Food and Drug Administration (2020) ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RTqPCR) Detection Kit - Letter of Authorization. 03 Apr 2020. Available at: https://www.fda.gov/media/136688/download (accessed 08 Apr 2020)
133. ScienCell (2020) ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit. 03 Apr 2020. Available at: https://www.fda.gov/media/136691/download (accessed 08 Apr 2020)
134. ScienCell (2020) SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (CVPD). 24 Jan 2020. Available at: https://www.sciencellonline.com/PS/7038.pdf (accessed 08 Apr 2020)
135. LexaGene (2020) LexaGene Analyzer Designed to Detect Pathogens like Coronavirus. 27 Jan 2020. Available at: https://lexagene.com/release/2020/lexagene-analyzer-designed-to-detect-pathogens-like-coronavirus/ (accessed 06 Feb 2020)
136. LeMieux J (2020) Detecting Coronavirus Cases as Outbreak Grows. Genetic Engineering & Biotechnology News,. 29 Jan 2020. Available at: https://www.genengnews.com/news/detecting-coronavirus-cases-as-outbreak-grows/ (accessed 05 Feb 2020)
137. Liferiver Bio-Tech Corp (2020) Novel Coronavirus (2019-nCoV) Real Time RT-PCR Kit. Available at: http://www.liferiverbiotech.com/Pages/Activity.aspx?id=10 (accessed 05 Feb 2020)
138. Antibody-Antibodies.com (2020) Novel Coronavirus (2019-nCoV) Real Time RT-PCR Kit. Available at: https://antibody-antibodies.com/products/rr-0478-02/novel-coronavirus-2019-ncov-real-time-rt-pcr-kit-5235214/ (accessed 05 Feb 2020)
139. Liferiver Bio-Tech Corp (2020) Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes). Available at: http://www.liferiverbiotech.com/Pages/Activity.aspx?id=11 (accessed 06 Feb 2020)
140. Antibody-Antibodies.com (2020) Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes). Available at: https://antibody-antibodies.com/products/rr-0479-02/novel-coronavirus-2019-ncov-real-time-multiplex-rt-pcr-kit-detection-for-3-genes-5235213/ (accessed 06 Feb 2020)
141. GenScript (2020) 2019-nCoV qRT-PCR Detection Assay. 29 Jan 2020. Available at: https://www.genscript.com/2019-ncov-qrt-pcr-detection-assay.html (accessed 06 Feb 2020)
142. PR Newswire (2020) GenScript Launches Novel Coronavirus Detection Assay. 30 Jan 2020. Available at: https://www.prnewswire.com/news-releases/genscript-launches-novel-coronavirus-detection-assay-300996465.html (accessed 06 Feb 2020)
143. Philippidis A (2020) IDbyDNA to Advance Platform, Now Including Novel Coronavirus, Expand Commercial Operations. Genetic Engineering News. 29 Jan 2020. Available at: https://www.genengnews.com/news/idbydna-to-advance-platform-now-including-novel-coronavirus-expand-commercial-operations/ (accessed 05 Feb 2020)
144. Verdict Medical Devices (2020) IDbyDNA's Explify Respiratory Test can detect coronavirus. Available at: https://www.medicaldevice-network.com/news/idbydnas-explify-respiratory-test-can-detect-coronavirus/ (accessed 06 Feb 2020)
145. Beijing Ditan Hospital (2020) Development of a Simple, Fast and Portable Recombinase Aided Amplification Assay for 2019-nCoV. ClinicalTrials.gov. 29 Jan 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT04245631?recrs=ab&cond=coronavirus&draw=3&rank=5 (accessed 10 Feb 2020)
146. WebWire (2020) Mammoth Biosciences Announces Peer-Reviewed Validation Of Its Rapid, CRISPR-Based COVID-19 Diagnostic. Available at: https://www.webwire.com/ViewPressRel.asp?aId=258059 (accessed 22 April)

147. CerTest (2020) “We hope to finish shortly the development of a kit to diagnose Wuhan Coronavirus”. 30 Jan 2020. Available at: https://www.certest.es/news/we-hope-to-finish-shortly-the-development-of-a-kit-to-diagnose-wuhan-coronavirus/ (accessed 06 Feb 2020)
148. PR Newswire (2020) CerTest Biotec and BD Announce COVID-19 Diagnostic Test. 10 Mar 2020. Available at: https://www.prnewswire.com/news-releases/certest-biotec-and-bd-announce-covid-19-diagnostic-test-301020270.html (accessed 11 Mar 2020)
149. CerTest (2020) Viasure Real time PCR Detection Kits. Available at: https://www.certest.es/wp-content/uploads/2020/03/IU-NCO212enes0420-rev.01.pdf (accessed 22 April)
150. Biospace (2020) GENOMICA, PharmaMar Group, is developing a kit to detect the new Wuhan coronavirus. 30 Jan 2020. Available at: https://www.biospace.com/article/genomica-pharmamar-group-is-developing-a-kit-to-detect-the-new-wuhan-coronavirus/ (accessed 06 Feb 2020)
151. News-Medical (2020) GENOMICA is developing new Wuhan coronavirus diagnostic kit. 31 Jan 2020. Available at: https://www.news-medical.net/news/20200131/GENOMICA-is-developing-new-Wuhan-coronavirus-diagnostic-kit.aspx (accessed 06 Feb 2020)
152. Genomica (2020) COVID-19 Kits. Available at: http://genomica.com/covid-19/?lang=en
153. PharmaMar (2020) PharmaMar Group's GENOMICA diagnostic kits for COVID-19 coronavirus receive CE conformity marking. 06 Mar 2020. Available at: http://pharmamar.com/wp-content/uploads/2020/03/PR_diagnostics_kit_covid19_CE_DEF.pdf (accessed 11 Mar 2020)
154. Novacyt (2020) Launch of novel coronavirus test. 31 Jan 2020. Available at: https://novacyt.com/wp-content/uploads/2020/01/Launch-of-novel-coronavirus-test-ENGLISH.pdf (accessed 06 Feb 2020)
155. Bryant M (2020) Novacyt launches test for new coronavirus. 03 Feb 2020. Available at: https://www.bioworld.com/articles/432812-novacyt-launches-test-for-new-coronavirus (accessed 06 Feb 2020)
156. Genesig (2020) Novel Coronavirus Strain 2019-nCoV. Available at: https://www.genesig.com/products/10037-novel-coronavirus-strain-2019-ncov (accessed 30 Jan 2020)
157. Genesig (2020) Coronavirus (COVID-19) CE IVD. Available at: https://www.genesig.com/products/10039-coronavirus-covid-19-ce-ivd (accessed 12 Mar 2020)
158. US Food and Drug Administration (2020) Primerdesign Ltd COVID-19 genesig Real-Time PCR assay - Letter of Authorization. 20 Mar 2020. Available at: https://www.fda.gov/media/136306/download (accessed 23 Mar 2020)
159. GenMark Diagnostics (2020) ePlex® SARS-CoV-2 Test Assay Manual. 19 Mar 2020. Available at: https://www.fda.gov/media/136282/download (accessed 09 Apr 2020)
160. Organization WH (2020) Coronavirus (COVID-19) genesig® Real-Time PCR assay. Available at: https://www.who.int/diagnostics_laboratory/eul_0489_185_00_path_covid19_ce_ivd_ifu_issue_2.0.pdf?ua=1 (accessed 22 April)
161. GenomeWeb (2020) Novacyt Gets CE Mark for Coronavirus Test. 18 Feb 2020. Available at: https://www.genomeweb.com/regulatory-news-fda-approvals/novacyt-gets-ce-mark-coronavirus-test#.Xmir9qgzaUk (accessed 09 Mar 2020)
162. Reuters (2020) Novacyt Launches CE-IVD Marked Novel Coronavirus Test. 17 Feb 2020. Available at: https://www.reuters.com/article/brief-novacyt-launches-ce-ivd-marked-nov/brief-novacyt-launches-ce-ivd-marked-novel-coronavirus-test-idUSFWN2AH0JI (accessed 09 Mar 2020)
163. Loh T (2020) Roche’s New Coronavirus Test Could Speed Patient Screening. Bloomberg. 31 Jan 2020. Available at: https://www.bloomberg.com/news/articles/2020-01-30/roche-s-new-virus-test-could-speed-up-screening-of-patients (accessed 06 Feb 2020)
164. Roche (2020) Roche statement on 2019-nCoV (novel coronavirus). 31 Jan 2020. Available at: https://www.roche.com/dam/jcr:945deac2-dcbe-4ae0-a7a9-e9b903b142a2/en/roche-statement-on-2019-nCoV.pdf (accessed 06 Feb 2020)
165. Roche (2020) Roche’s cobas SARS-CoV-2 Test to detect novel coronavirus receives FDA Emergency Use Authorization and is available in markets accepting the CE mark 13 Mar 2020. Available at: https://www.roche.com/media/releases/med-cor-2020-03-13.htm (accessed 17 Mar 2020)

166. Roche (2020) cobas® SARS-CoV-2. 12 Mar 2020. Available at: https://www.fda.gov/media/136049/download (accessed 09 Apr 2020)
167. Authority HS (2020) Provisional Authorisation for COVID-19 Tests. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/roche_provisional-authorisation-for-covid-19-tests_17042020.pdf
168. Tan A (2020) Coronavirus: Made-in-Singapore diagnostics test rolled out at some hospitals here. The Straits Times. 08 Feb 2020. Available at: https://www.straitstimes.com/singapore/health/coronavirus-made-in-singapore-diagnostics-test-implemented-at-hospitals-here (accessed 10 Feb 2020)
169. GenomeWeb (2020) Singapore Clears New SARS-CoV-2 Assay for Clinical Use. 03 Mar 2020. Available at: https://www.genomeweb.com/pcr/singapore-clears-new-sars-cov-2-assay-clinical-use#.XmirwqgzaUk (accessed 11 Mar 2020)
170. A*STAR. COVID-19 news. In:2020.
171. GeneFirst (2020) GeneFirst develops real-time PCR tests for detection of the new coronavirus 2019-nCoV. 03 Feb 2020. Available at: https://www.genefirst.com/copy-of-innovate-shanghai-grant (accessed 06 Feb 2020)
172. Kim S-g et al (2020) Korean firms rush to roll out commercial diagnostic kits for coronavirus. Pulse. 03 Feb 2020. Available at: https://pulsenews.co.kr/view.php?year=2020&no=108967 (accessed 05 Feb 2020)
173. Jeong S-i (2020) Korea approves 2 more COVID-19 detection kits for urgent use. Korea Biomedical Review. 28 Feb 2020. Available at: http://www.koreabiomed.com/news/articleView.html?idxno=7561 (accessed 12 Mar 2020)
174. GenomeWeb (2020) Kogene Biotech Novel Coronavirus Test Gets Regulatory Approvals in Korea. GenomeWeb. 10 Feb 2020. Available at: https://www.genomeweb.com/pcr/kogene-biotech-novel-coronavirus-test-gets-regulatory-approvals-korea#.XkTVuFIzYcg
175. PCL (2020) PCL COVID-19 Product Description. 17 March 2020. Available at: http://www.pclchip.com/eng/sub_n4/4_6.php?mode=view&number=783&page=1&b_name=eng_notice (accessed 7 May)
176. iHealthtech (2020) Developing novel coronavirus rapid detection kit. 03 Feb 2020. Available at: https://ihealthtech.nus.edu.sg/news/developing-novel-coronavirus-rapid-detection-kit/ (accessed 06 Mar 2020)
177. Johnson M (2020) As Worries Grow Over Novel Coronavirus, Dx Industry Jumps Into Action. GenomeWeb. 04 Feb 2020. Available at: https://www.genomeweb.com/pcr/worries-grow-over-novel-coronavirus-dx-industry-jumps-action#.Xjux9GgzaUl (accessed 06 Feb 2020)
178. Biomeme I (2020) COVID-19 Go-Strips. Available at: https://shop.biomeme.com/products/covid-19 (accessed 25 Feb 2020)
179. LabPulse (2020) Germany's Genekam rolls out Wuhan coronavirus test. 04 Feb 2020. Available at: https://www.labpulse.com/index.aspx?sec=sup&sub=mic&pag=dis&ItemID=800737 (accessed 06 Feb 2020)
180. Genekam (2020) Corona Virus 2020 (WUHAN STRAIN)*. 05 Feb 2020. Available at: http://genekam.de/corona-virus-2020-wuhan-strain.php (accessed 06 Feb 2020)
181. Genekam (2020) Fluhunter: Novel Coronavirus 2020 (Wuhan strain specific) –Realtime. Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR475-Wuhan%20specific-coronavirus-realtime-single-check.pdf (accessed 06 Feb 2020)
182. Genekam (2020) Fluhunter: REAL TIME – Coronavirus (Wuhan) and bat coronaviruses. Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR476-coronavirus2020%20and%20bat%20virusesrealtime.pdf (accessed 06 Feb 2020)
183. Genekam (2020) Fluhunter: Realtime Coronavirus (Wuhan strain), bat coronaviruses and MERS Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR477-Wuhan-bat%20coronavirus%20and%20MERS.pdf (accessed 06 Feb 2020)
184. Genekam (2020) Fluhunter: REAL TIME – Coronavirus 2020 Wuhan und Influenza A Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR479-novel%20coronavirus%202020%20and%20influenzaA-realtime.pdf (accessed 06 Feb 2020)
185. Thermo Fisher Scientific (2020) Genetic Analysis Solutions for Coronavirus 2019-nCoV. Available at: https://www.thermofisher.com/sg/en/home/clinical/clinical-genomics/pathogen-detection-solutions/genetic-analysis-coronavirus-2019-nCoV.html (accessed 06 Feb 2020)
186. Thermo Fisher Scientific (2020) FDA Issues Emergency Use Authorization to Thermo Fisher Scientific for Diagnostic Test Used to Detect COVID-19. 13 Mar 2020. Available at: https://ir.thermofisher.com/investors/news-and-events/news-releases/news-release-

details/2020/FDA-Issued-Emergency-Use-Authorization-to-Thermo-Fisher-Scientific-for-Diagnostic-Test-Used-to-Detect-COVID-19-on-March-13/default.aspx (accessed 17 Mar 2020)
187. Thermo Fisher Scientific (2020) TaqPath™ COVID-19 Combo Kit - Instructions for Use. 13 Mar 2020. Available at: https://www.fda.gov/media/136112/download (accessed 09 Apr 2020)
188. Thermo Fisher Scientific (2020) Thermo Fisher Scientific Receives CE Mark for its Diagnostic Test to Detect COVID-19. 26 Mar 2020. Available at: https://ir.thermofisher.com/investors/news-and-events/news-releases/news-release-details/2020/Thermo-Fisher-Scientific-Receives-CE-Mark-for-its-Diagnostic-Test-to-Detect-COVID-19/default.aspx (accessed 31 Mar 2020)
189. US Centers for Disease Control and Prevention (2020) CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel 15 Mar 2020. Available at: https://www.fda.gov/media/134922/download (accessed 09 Apr 2020)
190. US Food and Drug Administration (2020) Smart Detect SARS-CoV-2 rRT-PCR Kit (InBios) - Letter of Authorization. 07 Apr 2020. Available at: https://www.fda.gov/media/136787/download (accessed 08 Apr 2020)
191. Livzon (2020) Voluntary announcement progress of research and development products by a controlling subsidiary. 04 Feb 2020. Available at: https://www1.hkexnews.hk/listedco/listconews/sehk/2020/0213/2020021301032.pdf (accessed 21 Feb 2020)
192. LIVZON (2020) COVID-19 news Available at: https://www1.hkexnews.hk/listedco/listconews/sehk/2020/0204/2020020400006_c.pdf
193. Ho D et al (2020) Hong Kong researchers create fastest coronavirus diagnostic test to date. BioWorld. 07 Feb 2020. Available at: https://www.bioworld.com/articles/432927-hong-kong-researchers-create-fastest-coronavirus-diagnostic-test-to-date (accessed 10 Feb 2020)
194. The Hong Kong University of Science and Technology (2020) HKUST Research Team Invents World's Fastest Coronavirus Detection Device Offering Diagnostic Results in 40 Minutes. 06 Feb 2020. Available at: https://www.ust.hk/news/research-and-innovation/hkust-research-team-invents-worlds-fastest-coronavirus-detection (accessed 10 Feb 2020)
195. Tan A (2020) Coronavirus: Genomic 'red flags' to determine if patients are infected with virus originating from Wuhan. . The Straits Times. 7 Feb 2020. Available at: https://www.straitstimes.com/singapore/health/coronavirus-genomic-red-flags-to-determine-if-patients-are-infected-with-virus (accessed 19 Feb 2020)
196. Authority HS (2020) Provisional Authorisation for COVID-19 tests Acu-Corona 2.0. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/acumen-research-laboratories-pte-ltd.pdf
197. Authority HS (2020) Provisional Authorisation for COVID-19 tests AcuCorona 3.0. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/acumen-research-laboratories-pte-ltd---acu-corona-3-0.pdf (accessed 22 April)
198. Butkus B (2020) Qiagen Readying Updated Respiratory Panel for Emergency 2019-nCoV Testing. 11 Feb 2020. Available at: https://www.genomeweb.com/pcr/qiagen-readying-updated-respiratory-panel-emergency-2019-ncov-testing#.XkT5hC17Ech (accessed 13 Feb 2020)
199. US Food and Drug Administration (2020) QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN) - Letter of Authorization. 30 Mar 2020. Available at: https://www.fda.gov/media/136569/download (accessed 31 Mar 2020)
200. QIAGEN (2020) QIAstat-Dx Respiratory SARS-CoV-2 Panel. Available at: https://www.qiagen.com/us/products/instruments-and-automation/pcr-instruments/qiastat-dx-eua-us/#orderinginformation (accessed 31 Mar 2020)
201. QIAGEN (2020) QIAGEN releases QIAstat-Dx test kit to the U.S. as first syndromic test for detection of SARS-CoV-2 coronavirus under new FDA Policy. Available at: https://corporate.qiagen.com/newsroom/press-releases/2020/20200323_qiastat_covid19_fda (accessed 22 April)
202. Gov.uk (2020) PHE novel coronavirus diagnostic test rolled out across UK. 07 Feb 2020. Available at: https://www.gov.uk/government/news/phe-novel-coronavirus-diagnostic-test-rolled-out-across-uk (accessed 11 Feb 2020)
203. NHS (2020) COVID-19 virus testing in NHS laboratories. Available at: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf (accessed 22 April)

204. Cepheid (2020) Cepheid Announces Development of Test for New Coronavirus Strain (2019-nCoV). 10 Feb 2020. Available at: http://cepheid.mediaroom.com/2020-02-10-Cepheid-Announces-Development-of-Test-for-New-Coronavirus-Strain-2019-nCoV (accessed 02 Mar 2020)
205. Cepheid (2020) Xpert® Xpress SARS-CoV-2. 20 Mar 2020. Available at: https://www.fda.gov/media/136315/download (accessed 09 Apr 2020)
206. Health AGDo (2020) COVID-19 test kits included on the ARTG for legal supply in Australia. Available at: https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia (accessed 22 April)
207. Mobidiag (2020) Development of Novodiag® assay for safe and easy molecular testing of novel coronavirus and influenza viruses 10 Feb 2020. Available at: https://mobidiag.com/2020/02/10/development-of-novodiag-assay-for-safe-and-easy-molecular-testing-of-novel-coronavirus-and-influenza-viruses/ (accessed 02 Mar 2020)
208. Mobidiag (2020) A complete solution for rapid diagnostics of coronavirus infection. Available at: https://mobidiag.com/products/coronavirus-1/#Novodiag-COVID-19 (accessed 22 April)
209. Newsfile (2020) Sona Develops Rapid Screening Test for Coronavirus. 10 Feb 2020. Available at: https://www.newsfilecorp.com/release/52268/Sona-Develops-Rapid-Screening-Test-for-Coronavirus (accessed 03 Mar 2020)
210. SONA (2020) What is Sona's coronavirus test? Available at: sonanano.com/coronavirus/ (accessed 22 April)
211. Newsfile (2020) Sona announces key partner for Coronavirus Rapid Screening Test. 13 Feb 2020. Available at: https://www.newsfilecorp.com/release/52396/Sona-announces-key-partner-for-Coronavirus-Rapid-Screening-Test (accessed 03 Mar 2020)
212. London Stock Exchange (2020) HiberGene to collaborate on Coronavirus test. 11 Feb 2020. Available at: https://www.londonstockexchange.com/exchange/news/market-news/market-news-detail/other/14417997.html (accessed 03 Mar 2020)
213. Hamilton P (2020) Coronavirus test fast-tracked by Dublin company Hibergene. The Irish Times. 12 Feb 2020. Available at: https://www.irishtimes.com/business/health-pharma/coronavirus-test-fast-tracked-by-dublin-company-hibergene-1.4170798 (accessed 02 Mar 2020)
214. Molbio (2020) TruenatTM Beta CoV: Chip-based Real time PCR Test for Beta Coronavirus. Available at: http://www.molbiodiagnostics.com/product_details.php?id=54 (accessed 23 April)
215. G.B. S (2020) Performance evaluation of TruenatTM BETA CoV test on TrueLabTM workstation: Validation Report. Available at: http://www.molbiodiagnostics.com/uploads/product_evaluation/18_productevaluation_1820200406.180428.pdf (accessed 22 April)
216. Today B. Coronavirus crisis: ICMR allows TB-testing machine to boost screening process. In. New Delhi2020.
217. Array S (2020) COVID-19 Detection. Available at: https://www.star-array.com/copy-of-antimicrobial-resistance (accessed 22 April)
218. Nicola S (2020) A Berlin Biotech Company Got a Head Start on Coronavirus Tests. Bloomberg. 12 Mar 2020. Available at: https://www.bloomberg.com/news/articles/2020-03-12/a-berlin-biotech-company-got-a-head-start-on-coronavirus-tests (accessed 12 Mar 2020)
219. Zhou N et al (2020) First Australian evacuees set to leave Christmas Island after no reported cases of coronavirus. The Guardian. 16 Feb 2020. Available at: https://www.theguardian.com/world/2020/feb/16/first-group-of-australian-evacuees-set-to-leave-christmas-island-with-no-reported-cases-of-coronavirus (accessed 26 Mar 2020)
220. Chang C (2020) How the test for coronavirus works. Daily Mercury. 07 Mar 2020. Available at: https://www.dailymercury.com.au/news/how-the-test-for-coronavirus-works/3962036/ (accessed 26 Mar 2020)
221. GenomeWeb (2020) AusDiagnostics Gets CE Mark for Multiplex Coronavirus, Flu, RSV Assay. 23 Mar 2020. Available at: https://www.genomeweb.com/molecular-diagnostics/ausdiagnostics-gets-ce-mark-multiplex-coronavirus-flu-rsv-assay#.XnxetagzaUk (accessed 26 Mar 2020)
222. GenomeWeb (2020) Seegene Gets Emergency Use Approval in Korea for Novel Coronavirus Test. 18 Feb 2020. Available at: https://www.genomeweb.com/pcr/seegene-gets-emergency-use-approval-korea-novel-coronavirus-test#.Xk3ffJMzYgo (accessed 20 Feb 2020)

223. PR Newswire (2020) Seegene launches KFDA Approved COVID-19 Assay. 18 Feb 2020. Available at: https://www.prnewswire.com/news-releases/seegene-launches-kfda-approved-covid-19-assay-301005858.html (accessed 21 Feb 2020)
224. Seegene (2020) Allplex™ 2019-nCoV Assay: Simultaneous detection and identification of 3 target genes specific for COVID-19 Available at: http://www.seegene.com/assays/allplex_2019_ncov_assay (accessed 22 April)
225. Kim S-g et al (2020) Korean IVD firms fast-tracked to roll out COVID-19 test kits. 02 Mar 2020. Available at: https://pulsenews.co.kr/view.php?year=2020&no=218001 (accessed 12 Mar 2020)
226. Authority HS (2020) Provisional authorisation for COVID-19 test: Seegene AllplexTM 2019-nCoV Assay Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/all-eights-(singapore)-pte-ltd.pdf (accessed 22 April)
227. Credo Diagnostics Biomedical (2020) Credo Diagnostics Biomedical is finalizing a rapid point-of-care molecular test for the detection of novel Coronavirus COVID-19 in 20 minutes. 21 Feb 2020. Available at: https://www.credodxbiomed.com/zh-cn/news/97-credo-diagnostics-biomedical-is-finalizing-a-rapid-test-for-the-covid-19 (accessed 08 Apr 2020)
228. Credo Diagnostics Biomedical (2020) Credo Diagnostics Biomedical VitaPCR SARS-CoV-2 Assay Garners CE Mark. 17 Mar 2020. Available at: https://credodxbiomed.com/en/news/100-credo-diagnostics-biomedical-vitapcr-sars-cov-2-assay-garners-ce-mark (accessed 08 Apr 2020)
229. SolGent (2020) DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit CE-IVD. Available at: http://www.solgent.com/english/sub03020102/view/id/45 (accessed 12 Mar 2020)
230. SD Biosensor (2020) STANDARD M nCoV Real-Time Detection kit, Instructions for Use. 24.04.2020. Available at: https://www.fda.gov/media/137302/download (accessed 30 April)
231. SD Biosensor (2020) STANDARD M nCoV Real-Time Detection kit. Available at: http://www.sdbiosensor.com/xe/product/7653 (accessed 22 April)
232. ELITech Group (2020) Coronavirus (COVID 19): New CE-IVD Kit now available worldwide. 03 Mar 2020. Available at: https://www.elitechgroup.com/news/coronavirus-covid-19-new-ce-ivd-kit-now-available-worldwide (accessed 11 Mar 2020)
233. GenomeWeb (2020) OsangHealthcare Gets CE Mark for SARS-CoV-2 Detection Kit. 04 Mar 2020. Available at: https://www.genomeweb.com/molecular-diagnostics/osanghealthcare-gets-ce-mark-sars-cov-2-detection-kit#.XmicAKgzaUl (accessed 11 Mar 2020)
234. FDA (2020) GeneFinder™ COVID-19 Plus RealAmp Kit. Available at: https://www.fda.gov/media/137116/download (accessed 22 April)
235. US Department of Health & Human Services (2020) HHS Supports Mesa Biotech to Develop a Rapid Diagnostic to Detect Novel Coronavirus Infections. 18 Mar 2020. Available at: https://www.hhs.gov/about/news/2020/03/18/hhs-supports-mesa-biotech-develop-rapid-diagnostic-detect-novel-coronavirus-infections.html (accessed 03 Apr 2020)
236. PR Newswire (2020) Mesa Biotech Developing Molecular Point-of-Care (PCR) Diagnostic Test for Novel Coronavirus (COVID-19). 04 Mar 2020. Available at: https://www.prnewswire.com/news-releases/mesa-biotech-developing-molecular-point-of-care-pcr-diagnostic-test-for-novel-coronavirus-covid-19-301015955.html (accessed 03 Apr 2020)
237. Mesa Biotech (2020) Accula™ SARS-CoV-2 Test. 23 Mar 2020. Available at: https://www.fda.gov/media/136355/download (accessed 09 Apr 2020)
238. Newswire P (2020) Luminex Receives FDA Emergency Use Authorization for NxTAG® CoV Extended Panel to Detect the SARS-CoV-2 Virus that Causes COVID-19 Disease. 27 Mar 2020. Available at: https://www.prnewswire.com/news-releases/luminex-receives-fda-emergency-use-authorization-for-nxtag-cov-extended-panel-to-detect-the-sars-cov-2-virus-that-causes-covid-19-disease-301031132.html (accessed 31 Mar 2020)
239. Luminex (2020) Flexible Testing Options for SARS-CoV-2 Coronavirus. Available at: http://info.luminexcorp.com/covid19 (accessed 31 Mar 2020)
240. Luminex (2020) Luminex Provides Updates on Critical Efforts Related to Novel Coronavirus. 04 Mar 2020. Available at: https://investor.luminexcorp.com/news-releases/news-release-details/luminex-provides-updates-critical-efforts-related-novel (accessed 31 Mar 2020)
241. US Food and Drug Administration (2020) ARIES SARS-CoV-2 Assay (Luminex) - Letter of Authorization. 03 Apr 2020. Available at: https://www.fda.gov/media/136694/download (accessed 08 Apr 2020)
242. Luminex (2020) ARIES® SARS-CoV-2 Assay Package Insert. 03 Apr 2020. Available at: https://www.fda.gov/media/136693/download (accessed 08 Apr 2020)

243. Genomica (2020) Spanish Biotech Company Receive CE-IVD Marking on Two Covid-19 Diagnostic Test Kits. rapidmicrobiology. 10 Mar 2020. Available at: https://www.rapidmicrobiology.com/news/spanish-biotech-company-receive-ce-ivd-marking-on-two-covid-19-diagnostic-test-kits (accessed 11 Mar 2020)
244. US Food and Drug Administration (2020) SARS-CoV-2 Fluorescent PCR Kit (Maccura Biotechnology) - Letter of Authorization.pdf. 15 Apr 2020. Available at: https://www.fda.gov/media/137023/download (accessed 16 Apr 2020)
245. Business Wire (2020) Avellino Labs Announces Availability of New FDA-Recognized Genetic Test for Coronavirus. 09 Mar 2020. Available at: https://www.businesswire.com/news/home/20200309005194/en/Avellino-Labs-Announces-Availability-New-FDA-Recognized-Genetic (accessed 31 Mar 2020)
246. Avellino Lab (2020) Accelerated Emergency Use Authorization (EUA) Summary AvellioCoV2 Test. 25 Mar 2020. Available at: https://www.fda.gov/media/136453/download (accessed 09 Apr 2020)
247. US Food and Drug Administration (2020) QuantiVirus SARS-CoV-2 Test kit (DiaCarta) - Letter of Authorization. 08 Apr 2020. Available at: https://www.fda.gov/media/136806/download (accessed 11 Apr 2020)
248. Wadsworth Center (2020) New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel. 29 Feb 2020. Available at: https://www.fda.gov/media/135847/download (accessed 09 Apr 2020)
249. BioSearch Technologies (2020) 2019-nCoV CDC-qualified Probe and Primer Kits for SARS-CoV-2. Available at: https://www.biosearchtech.com/products/pcr-kits-and-reagents/pathogen-detection/2019-ncov-cdc-probe-and-primer-kit-for-sars-cov-2# (accessed 18 March 2020)
250. GenomeWeb (2020) Coronavirus Test From GenMark Diagnostics Submitted to FDA for Emergency Use Authorization 11 Mar 2020. Available at: https://www.genomeweb.com/molecular-diagnostics/coronavirus-test-genmark-diagnostics-submitted-fda-emergency-use-authorization#.XnBshZMzYci (accessed 17 Mar 2020)
251. US Food and Drug Administration (2020) qSARS-CoV-2 IgG/IgM Rapid Test (Cellex) - Letter of Authorization. 01 Apr 2020. Available at: https://www.fda.gov/media/136622/download (accessed 02 Apr 2020)
252. GenMark Diagnostics (2020) GenMark Receives FDA Emergency Use Authorization for its ePlex® SARS-CoV-2 Test. Available at: http://ir.genmarkdx.com/news-releases/news-release-details/genmark-receives-fda-emergency-use-authorization-its-eplexr-sars (accessed 22 April)
253. Han AP (2020) Fulgent Genetics Developing PCR, NGS Coronavirus Diagnostic Tests. 11 Mar 2020. Available at: https://www.genomeweb.com/molecular-diagnostics/coronavirus-test-genmark-diagnostics-submitted-fda-emergency-use-authorization#.XnBshZMzYci (accessed 17 Mar 2020)
254. Fulgent (2020) CORONAVIRUS DISEASE (COVID-19) VIRUS TESTING. Available at: https://www.fulgentgenetics.com/content/forms/TRF_COVID19-V3-FILLABLE-RTPCR.pdf (accessed 22 April)
255. bioMérieux (2020) bioMérieux receives Emergency Use Authorization for BIOFIRE® COVID-19 test. 24 Mar 2020. Available at: https://www.biomerieux.com/en/biomerieux-receives-emergency-use-authorization-biofirer-covid-19-test (accessed 26 Mar 2020)
256. bioMérieux (2020) First of 3 diagnostic tests for SARS-CoV-2 coronavirus available from bioMérieux 11 Mar 2020. Available at: https://www.biomerieux.com/en/first-3-diagnostic-tests-sars-cov-2-coronavirus-available-biomerieux (accessed 26 Mar 2020)
257. US Food and Drug Administration (2020) BioFire COVID-19 Test (BioFire Defense) - Letter of Authorization. 23 Mar 2020. Available at: https://www.fda.gov/media/136356/download (accessed 26 Mar 2020)
258. BioFire Defense (2020) BioFire® COVID-19 Test - Instructions for Use. 23 Mar 2020. Available at: https://www.fda.gov/media/136353/download (accessed 09 Apr 2020)
259. US Food and Drug Administration (2020) NeuMoDx SARS-CoV-2 Assay (NeuMoDx Molecular Inc) - Letter of Authorization. 30 Mar 2020. Available at: https://www.fda.gov/media/136566/download (accessed 31 Mar 2020)
260. NeuMoDx Molecular (2020) Preparing to Launch Coronavirus Test. 12 Mar 2020. Available at: https://www.neumodx.com/preparing-to-launch-coronavirus-test/ (accessed 31 Mar 2020)
261. NeuMoDx Molecular (2020) NeuMoDx™ SARS-CoV-2 Assay - Instructions For Use. 30 Mar 2020. Available at: https://www.fda.gov/media/136565/download (accessed 11 Apr 2020)

262. GenomeWeb (2020) Mount Sinai-Led Consortium, Fluidigm Developing Epigenetic Coronavirus Dx. 16 Mar 2020. Available at: https://www.genomeweb.com/pcr/mount-sinai-led-consortium-fluidigm-developing-epigenetic-coronavirus-dx#.XnBZB5MzYgp (accessed 17 Mar 2020)
263. Hologic (2020) Hologic's Molecular Test for the Novel Coronavirus, SARS-CoV-2, Receives FDA Emergency Use Authorization 16 Mar 2020. Available at: https://investors.hologic.com/press-releases/press-release-details/2020/Hologics-Molecular-Test-for-the-Novel-Coronavirus-SARS-CoV-2-Receives-FDA-Emergency-Use-Authorization/default.aspx (accessed 17 Mar 2020)
264. US Food and Drug Administration (2020) iAMP COVID-19 Detection Kit (Atila BioSystems) - Letter of Authorization. 10 Apr 2020. Available at: https://www.fda.gov/media/136872/download (accessed 16 Apr 2020)
265. Hologic (2020) SARS-CoV-2 Assay (Panther Fusion® System). 16 Mar 2020. Available at: https://www.fda.gov/media/136156/download (accessed 09 Apr 2020)
266. NS Medical Devices (2020) Hologic gets FDA's EUA status for Panther Fusion SARS-CoV-2 assay Available at: https://www.nsmedicaldevices.com/news/hologic-panther-fusion-sars/
267. LabCorp (2020) LabCorp COVID-19 RT-PCR test EUA Summary. 16 Mar 2020. Available at: https://www.fda.gov/media/136151/download (accessed 09 Apr 2020)
268. LabCorp (2020) Q & A, Labcorp's Testing for COVID-19. Available at: https://www.labcorp.com/assets-media/2330 (accessed 22 April)
269. US Food and Drug Administration (2020) Lyra SARS-CoV-2 Assay (Quidel Corp.) - Letter of Authorization. 17 Mar 2020. Available at: https://www.fda.gov/media/136224/download (accessed 18 Mar 2020)
270. Quidel (2020) Lyra® SARS-CoV-2 Assay 10 - Instructions for Use. 23 Mar 2020. Available at: https://www.fda.gov/media/136227/download (accessed 09 Apr 2020)
271. Quidel (2020) Lyra SARS-CoV-2 Assay Instructions for Use. Available at: https://www.fda.gov/media/136820/download (accessed 22 April)
272. US Food and Drug Administration (2020) Quest SARS-CoV-2 rRT-PCR (Quest Diagnostics Infectious Disease) - Letter of Authorization. 17 Mar 2020. Available at: https://www.fda.gov/media/136228/download (accessed 18 Mar 2020)
273. Quest Diagnostics (2020) SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Test Code 39433). Available at: https://www.fda.gov/media/136231/download (accessed 09 Apr 2020)
274. BD (2020) BioGX SARS-CoV-2 Reagents for BD MAX™ System Available at: https://www.fda.gov/media/136653/download (accessed 08 Apr 2020)
275. Park A (2020) Becton Dickinson Seeks Emergency FDA Approval for a Two-Hour Coronavirus Test. Time. 17 Mar 2020. Available at: https://time.com/5804222/two-hour-coronavirus-test/ (accessed 08 Apr 2020)
276. US Food and Drug Administration (2020) BioGX SARS-CoV-2 Reagents for BD MAX System (BD) - Letter of Authorization. 02 Apr 2020. Available at: https://www.fda.gov/media/136650/download (accessed 08 Apr 2020)
277. Abbott (2020) Abbott Launches Novel Coronavirus Test. 18 Mar 2020. Available at: https://www.abbott.com/corpnewsroom/product-and-innovation/abbott-launches-novel-coronavirus-test.html (accessed 23 Mar 2020)
278. Abbott (2020) Abbott RealTime SARS-CoV-2. 18 Mar 2020. Available at: fda.gov/media/136258/download (accessed 09 Apr 2020)
279. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Abbott Realtime SARS-CoV-2 assay. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/abbott-laboratories-(singapore)-pte-ltd.pdf (accessed 22 April)
280. DiaSorin Molecular (2020) DiaSorin Molecular COVID-19 Test Has Received FDA Emergency Use Authorization. 20 Mar 2020. Available at: https://molecular.diasorin.com/international/wp-content/uploads/2020/03/DiaSorin-Molecular-COVID-19-EUA-APPROVED.pdf (accessed 23 Mar 2020)
281. US Food and Drug Administration (2020) Simplexa COVID-19 Direct assay (DiaSorin Molecular) - Letter of Authorization. 19 Mar 2020. Available at: https://www.fda.gov/media/136288/download (accessed 23 Mar 2020)
282. Diasorin Molecular (2020) Simplexa™ COVID-19 Direct. 19 Mar 2020. Available at: https://www.fda.gov/media/136286/download (accessed 09 Apr 2020)
283. Business Wire (2020) New Studies Find Bio-Rad's QX200 Droplet Digital PCR System Can Detect COVID-19 With Greater Sensitivity and Precision Than Other Existing Molecular Tests. 19 Mar 2020. Available at:

https://www.businesswire.com/news/home/20200319005825/en/New-Studies-Find-Bio-Rad%E2%80%99s-QX200-Droplet-Digital (accessed 02 Apr 2020)
284. Johnson M (2020) Bio-Rad Laboratories ddPCR Shows Accuracy Benefits in COVID-19 Detection Studies. GenomeWeb. 29 Mar 2020. Available at: https://www.genomeweb.com/pcr/bio-rad-laboratories-ddpcr-shows-accuracy-benefits-covid-19-detection-studies#.XoYVRtMzbu2 (accessed 03 Apr 2020)
285. Bio-Rad (2020) SARS-CoV-2 / COVID-19 Assay and Research Solutions. Available at: https://www.bio-rad.com/featured/en/coronavirus-covid-19-assay-development-vaccine-research.html (accessed 03 Apr 2020)
286. Biodesix (2020) Biodesix SARS-CoV-2 Droplet Digital™ PCR (ddPCR™) Test; FAQs. Available at: https://www.biodesix.com/products/covid-19 (accessed 22 April)
287. Liu D et al (2020) Europe Pulls Out All the Stops to Approve Covid-19 Test Kits From China. Caixin Global. 22 Mar 2020. Available at: https://www.caixinglobal.com/2020-03-22/europe-pulls-out-all-the-stops-to-approve-covid-19-test-kits-from-china-101532386.html (accessed 17 Apr 2020)
288. Maccura Biotechnology (2020) SARS-CoV-2 Fluorescent PCR Kit 15 Apr 2020. Available at: https://www.fda.gov/media/137026/download (accessed 16 Apr 2020)
289. PR Newswire (2020) DiaCarta Inc. has filed for EUA with the FDA and has received CE mark for its highly sensitive QuantiVirus™ SARS-CoV-2 Test. 24 Mar 2020. Available at: https://www.prnewswire.com/news-releases/diacarta-inc-has-filed-for-eua-with-the-fda-and-has-received-ce-mark-for-its-highly-sensitive-quantivirus-sars-cov-2-test-301028698.html (accessed 26 Mar 2020)
290. WCG FDAnews (2020) DiaCarta Earns CE Mark for Coronavirus Test. 24 Mar 2020. Available at: https://www.fdanews.com/articles/196365-diacarta-earns-ce-mark-for-coronavirus-test (accessed 26 Mar 2020)
291. PerkinElmer (2020) New Coronavirus (2019-nCoV) Nucleic Acid Detection Kit. Available at: https://perkinelmer-appliedgenomics.com/home/products/new-coronavirus-2019-ncov-nucleic-acid-detection-kit/ (accessed 26 Mar 2020)
292. PerkinElmer (2020) Instructions for PerkinElmer® New Coronavirus Nucleic Acid Detection Kit v 3.0. 24 Mar 2020. Available at: https://www.fda.gov/media/136410/download (accessed 09 Apr 2020)
293. FDA (2020) Trade/Device Name: PerkinElmer New Coronavirus Nucleic Acid Detection Kit. Available at: https://www.fda.gov/media/136616/download (accessed 22 April)
294. Abbott (2020) Abbott Launches Molecular Point-of-Care Test to Detect Novel Coronavirus in as Little as Five Minutes. 27 Mar 2020. Available at: https://abbott.mediaroom.com/2020-03-27-Abbott-Launches-Molecular-Point-of-Care-Test-to-Detect-Novel-Coronavirus-in-as-Little-as-Five-Minutes (accessed 31 Mar 2020)
295. US Food and Drug Administration (2020) COV-19 IDx assay (Ipsum Diagnostics) - Letter of Authorization. 01 Apr 2020. Available at: https://www.fda.gov/media/136618/download (accessed 02 Apr 2020)
296. Ipsum Diagnostics (2020) EMERGENCY USE AUTHORIZATION (EUA) SUMMARY: The COV-19 IDx assay. 01 Apr 2020. Available at: https://www.fda.gov/media/136621/download (accessed 02 Apr 2020)
297. US Food and Drug Administration (2020) Gnomegen COVID-19 RT-Digital PCR Detection Kit - Letter of Authorization. 06 Apr 2020. Available at: https://www.fda.gov/media/136735/download (accessed 08 Apr 2020)
298. Gnomegen (2020) COVID-19 RT-Digital PCR Detection Kit - Instructions for Use. 06 Apr 2020. Available at: https://www.fda.gov/media/136738/download (accessed 08 Apr 2020)
299. InBios International (2020) Smart Detect™ SARS-CoV-2 rRT-PCR Kit - Instructions for Use. 07 Apr 2020. Available at: https://www.fda.gov/media/136786/download (accessed 08 Apr 2020)
300. InBios International (2020) Smart Detect™ SARS-CoV-2 rRT-PCR Kit. Available at: https://inbios.com/smart-detecttm-sars-cov-2-rrt-pcr-kit/ (accessed 08 Apr 2020)
301. Business Wire (2020) Genetron Health Announces Its Novel Coronavirus Nucleic Acid Detection Kit Is CE Marked and FDA-EUA Application Accepted, with Three Laboratories Passing NCCL's COVID-19 EQA. 07 Apr 2020. Available at: https://www.businesswire.com/news/home/20200407005572/en/ (accessed 08 Apr 2020)
302. US Food and Drug Administration (2020) BD SARS-CoV-2 Reagents for BD MAX System - Letter of Authorization. 08 Apr 2020. Available at: https://www.fda.gov/media/136813/download (accessed 11 Apr 2020)

303. BD (2020) SARS-CoV-2 Reagents for BD MAX System. 08 Apr 2020. Available at: https://www.fda.gov/media/136816/download (accessed 11 Apr 2020)
304. Atila BioSystems (2020) iAMP-COVID19-100 - Instructions For Use. 10 Apr 2020. Available at: https://www.fda.gov/media/136870/download (accessed 16 Apr 2020)
305. Atila BioSystems (2020) IAMP COVID-19 Detection Kit. Available at: https://atilabiosystems.com/covid-19-test-2/ (accessed 17 Apr 2020)
306. FDA (2020) GSTM COVID-19 Real-Time PCR Kit: For Emergency Use Authorization Only. Available at: https://www.fda.gov/media/137093/download (accessed 22 April)
307. FDA (2020) ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY CURATIVE-KORVA SARS-COV-2 ASSAY
(Curative-Korva, KorvaLabs Inc Clinical Laboratory). Available at: https://www.fda.gov/media/137089/download (accessed 22 April)
308. FDA (2020) Fosun COVID-19 RT-PCR Detection Kit Rx Only: For Emergency Use Authorization (EUA) only. Available at: https://www.fda.gov/media/137120/download (accessed 22 April)
309. Mobidiag (2020) Amplidiag® COVID-19 molecular diagnostic test granted emergency use authorization in Finland for novel coronavirus. Available at: https://mobidiag.com/2020/04/14/amplidiag-covid-19-molecular-diagnostic-test-granted-emergency-use-authorization-in-finland-for-novel-coronavirus/ (accessed 22 April)
310. SD Biosensor (2020) STANDARD F COVID-19 Ag FIA. Available at: http://www.sdbiosensor.com/xe/product/7677 (accessed 22 April)
311. Genetic Signatures (2020) Genetic Signatures CE-IVD approval now received for EasyScreen™ SARS-CoV-2 Detection Kit. Available at: https://geneticsignatures.com/us/genetic-signatures-ce-ivd-approval-now-received-for-easyscreen-sars-cov-2-detection-kit/ (accessed 22 April)
312. Liferiver M (2020) Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection of 3 Genes) User Manual. Available at: https://www.mobitec.com/media/liferiver/invitrodiagnostics/realtimepcrdiagnostickits/RR-0479-02-ZJ.pdf (accessed 22 April)
313. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: abTES™ COVID-19 qPCR I Kit. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/aitbiotech-pte-ltd.pdf (accessed 22 April)
314. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Real-Time PCR Assay for the Detection of SARSCoV-2 Virus. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/dso-national-laboratories.pdf (accessed 22 April)
315. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay). Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biowalker-pte-ltd.pdf (accessed 22 April)
316. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: ProTect™ COVID-19 RT-qPCR Kit Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/jn-medsys-pte-ltd.pdf (accessed 22 April)
317. news M (2020) Singapore's Camtech, JN Medsys to increase production of COVID-19 test kits. Available at: https://www.mobihealthnews.com/news/asia-pacific/singapore-s-camtech-jn-medsys-increase-production-covid-19-test-kits (accessed 22 April)
318. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: ViroKey SARS-CoV-2 RT-PCR Test. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/vela_provisional-authorisation-for-covid-19-tests_17042020.pdf (accessed 22 April)
319. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Cepheid® Xpert® Xpress SARS-CoV-2. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/spd-scientific-pte-ltd.pdf (accessed 22 April)
320. Health Sciences Authority (2020) Provisional Authorisation for COVID-19 Tests: PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/perkinelmer_provisional-authorisation-for-covid-19-tests_24042020.pdf (accessed 30 April)
321. Health Sciences Authority (2020) Provisional Authorisation for COVID-19 Test: BioWalker SARS-CoV-2 Assay. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biowalker_provisional-authorisation-for-covid-19-tests_24042020.pdf (accessed 30 April)
322. Health Sciences Authority (2020) Provisional Authorisation for COVID-19 Tests: Sansure Biotech Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit Available at:

https://www.hsa.gov.sg/docs/default-source/hprg-mdb/medicell_provisional-authorisation-for-covid-19-tests_24042020.pdf (accessed 30 April)
323. GenBody Inc. (2020) GenBody Covid-19 IgM/IgG: Differential detection of COVID-19 IgM and IgG. Available at: http://genbody.co.kr/bbs/board.php?bo_table=human01&wr_id=38&sca=COVID-19 (accessed 7 May)
324. World Health Organization (2020) Update on COVID-19 in vitro diagnostics listed by National Regulatory Authorities in IMDRF jurisdictions. Available at: https://www.who.int/diagnostics_laboratory/200406_imdrf_covid19_listing_update_6_april_2020.pdf (accessed 30 April)
325. CTK Biotech (2020) New! CTK launches Test kits for COVID-19. Available at: https://ctkbiotech.com/covid-19/ (accessed 30 April)
326. Seasun Biomaterials (2020) Covid-19 Test: Real-time PCR base Platform Available at: https://docs.google.com/document/d/1uHbdWHc2H9aGnAcoCjAk5RTivZNHI8mES8vrz_rZe8A/edit (accessed 7 May)
327. FDA (2020) U-TOP™ COVID-19 Detection Kit: For in vitro diagnostic use only. Available at: https://www.fda.gov/media/137425/download (accessed 7 May)
328. Rhoenix Inc (2020) Rhoenix Available at: https://rheonix.com/ (accessed 7 May)
329. FDA (2020) Rhoenix COVID-19™ MDx Assay. Available at: https://www.fda.gov/media/137489/download (accessed 7 May)
330. Lab Genomics (2020) Lab Genomics. Available at: https://labgenomic.com/ (accessed 7 May)
331. FDA (2020) Instructions for LabGun™ COVID-19 RT-PCR Kit. Available at: https://www.fda.gov/media/137483/download (accessed 7 May)
332. BioFire by BioMerius (2020) BioFire. Available at: https://www.biofiredx.com/ (accessed 7 May)
333. FDA (2020) BioFire® Respiratory Panel 2.1 (RP2.1). Available at: https://www.fda.gov/media/137583/download (accessed 7 May)
334. Bio-Rad (2020) Coronavirus SARS-CoV-2 / COVID-19 Assay and Research Solutions. Available at: https://www.bio-rad.com/ (accessed 7 May)
335. FDA (2020) Bio-Rad SARS-CoV-2 ddPCR Test. Available at: https://www.fda.gov/media/137579/download (accessed 7 May)
336. MPA (2020) 2019-nCoV, IgM/IgG. Available at: http://mpa.gd.gov.cn/xwdt/sjdt/content/post_2931192.html
337. TISENC (2020) Tianshen Medical, Shenzhen Third People's Hospital and Shenzhen University successfully developed the world's first single-person chemiluminescent novel coronavirus antibody detection kit and conducted clinical testing. 11 February 2020. Available at: http://www.tisenc.com/?p=13139 (accessed 22 April)
338. Meiping G (2020) Researchers develop new test kit to detect coronavirus in 15 mins. 11 Mar 2020. Available at: https://news.cgtn.com/news/2020-03-11/Researchers-develop-new-test-kit-to-detect-coronavirus-in-15-mins-OMjPu5DFEk/index.html (accessed 22 April)
339. Biomedical K (2020) Heavy! 15 minutes, multi-center clinical verification, the new rapid detection reagents of Jinzhun Biological original technology new coronary pneumonia was successfully developed! 19 Feb 2020. Available at: http://www.king-focus.com/2020-02-19_51988.html (accessed 22 April)
340. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method). Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/skyquest-pte-ltd.pdf (accessed 22 April)
341. EUROIMMUN AG (2020) Products - SARS-Coronavirus. Available at: https://www.euroimmun.com/products/indications/infektions-serologie/weitere-parameter/sars-coronavirus.html (accessed 02 Mar 2020)
342. EUROIMMUN AG (2020) Tests for detection of antibodies against SARS-CoV-2 now available. 21 Feb 2020. Available at: https://www.coronavirus-diagnostics.com (accessed 28 Feb 2020)
343. Stiba K (2020) Tests for detection of antibodies against SARS-CoV-2 now available. EUROIMMUNBlog. 21 Feb 2020. Available at: https://www.euroimmunblog.com/tests-for-detection-of-antibodies-against-sars-cov-2-now-available/ (accessed 28 Feb 2020)
344. EUROIMMUN AG (2020) Frequently asked questions on SARS-CoV. Available at: https://www.coronavirus-diagnostics.com/faq.html (accessed 22 April)
345. AG E (2020) Anti-SARS-CoV-2 ELISA (IgG): Instruction for use. Available at: https://www.fda.gov/media/137609/download (accessed 7 May)

346. EUROIMMUN AG (2020) Application of EUROIMMUN tests for COVID-19 diagnostics Available at: https://www.coronavirus-diagnostics.com/documents/Indications/Infections/Coronavirus/YI_2606_I_UK_B.pdf (accessed 22 April)
347. EUROIMMUN AG (2020) The complete package for the diagnostic of COVID-19. Available at: https://www.coronavirus-diagnostics.com/ (accessed 22 April)
348. BioSpace (2020) Scanwell Health to Launch First Clinical-Grade Rapid At-Home Test to Aid in COVID-19 Crisis. Available at: https://www.biospace.com/article/releases/scanwell-health-to-launch-first-clinical-grade-rapid-at-home-test-to-aid-in-covid-19-crisis/) (accessed 22 April)
349. Mologic (2020) Mologic and Institut Pasteur de Dakar launch accelerated programme to develop rapid diagnostic test for Ebola. 25 Feb 2020. Available at: https://mologic.co.uk/mologic-and-institut-pasteur-de-dakar-launch-accelerated-programme-to-develop-rapid-diagnostic-test-for-ebola/ (accessed 02 Apr 2020)
350. Mologic (2020) Mologic and partners begin validation process for COVID-19 point-of-need diagnostic test. 26 Mar 2020. Available at: https://mologic.co.uk/mologic-and-partners-begin-validation-process-for-covid-19-point-of-need-diagnostic-test/ (accessed 02 Apr 2020)
351. Mologic (2020) COVID-19 Update - 17 April 2020. Available at: https://mologic.co.uk/covid-19-update-17-april-2020/ (accessed 22 April)
352. 360Dx (2020) Snibe Diagnostic Receives CE Mark for SARS-CoV-2 Kits, Immunoassay System. 28 Feb 2020. Available at: https://www.360dx.com/regulatory-news-fda-approvals/snibe-diagnostic-receives-ce-mark-sars-cov-2-kits-immunoassay-system#.XmisJagzaUk (accessed 11 Mar 2020)
353. Snibe Diagnostic (2020) The world's first 2019-nCoV CLIA Kits received CE mark. 06 Mar 2020. Available at: http://www.snibe.com/zh_en/en_newsView.aspx?id=576 (accessed 11 Mar 2020)
354. Lippi G et al (2020) Assessment of immune response to SARS-CoV-2 with fully automated MAGLUMI 2019-nCoV IgG and IgM chemiluminescence immunoassays. (0):20200473. Available at: https://www.degruyter.com/view/journals/cclm/ahead-of-print/article-10.1515-cclm-2020-0473/article-10.1515-cclm-2020-0473.xml
355. Robinson M (2020) Polish firm looking to register ultra-fast coronavirus testing which can identify infection in 10 minutes. 02 Mar 2020. Available at: https://www.thefirstnews.com/article/polish-firm-looking-to-register-ultra-fast-coronavirus-testing-which-can-identify-infection-in-10-minutes-10839 (accessed 23 Mar 2020)
356. Medical Supply Company (2020) 2019-nCoV IgG/IgM Rapid Test (Single Use Kit). Available at: https://www.medical-supply.ie/product/2019-ncov-igg-igm-rapid-test-single-use-kit/ (accessed 23 Mar 2020)
357. Lee NY et al (2020) A case of COVID-19 and pneumonia returning from Macau in Taiwan: Clinical course and anti-SARS-CoV-2 IgG dynamic. *J Microbiol Immunol Infect.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32198005
358. Petrone J (2020) Iceni Diagnostics Developing Point-of-Care, Lateral Flow Assay for SARS-CoV-2. 360Dx. 20 Mar 2020. Available at: https://www.360dx.com/point-care-testing/iceni-diagnostics-developing-point-care-lateral-flow-assay-sars-cov-2#.XoW0jNMzYUs (accessed 02 Apr 2020)
359. US Food and Drug Administration (2020) DPP COVID-19 IgM/IgG System (Chembio Diagnostic Systems) - Letter of Authorization. 14 Apr 2020. Available at: https://www.fda.gov/media/136965/download (accessed 16 Apr 2020)
360. Chembio Diagnostic System (2020) DPP® COVID-19 IgM/IgG System. 14 Apr 2020. Available at: https://www.fda.gov/media/136963/download (accessed 16 Apr 2020)
361. Bloomberg (2020) Chembio Diagnostics Receives $4 Million Purchase Order from Bio-Manguinhos for Production of DPP COVID-19 IgM_IgG System in Brazil. 20 Mar 2020. Available at: https://www.bloomberg.com/press-releases/2020-03-20/chembio-diagnostics-receives-4-million-purchase-order-from-bio-manguinhos-for-production-of-dpp-covid-19-igm-igg-system-in (accessed 17 Apr 2020)
362. US Food and Drug Administration (2020) VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (Ortho Clinical Diagnostics) - Letter of Authorization. 14 Apr 2020. Available at: (accessed 16 Apr 2020)
363. Ortho Clinical Diagnostics (2020) Instructions for Use CoV2T 14 Apr 2020. Available at: https://www.fda.gov/media/136967/download (accessed 16 Apr 2020)

364. Medgadget (2020) Ortho Diagnostics Unveils COVID-19 Antibody Test. 06 Apr 2020. Available at: https://www.medgadget.com/2020/04/ortho-diagnostics-unveils-covid-19-antibody-test.html (accessed 17 Apr 2020)
365. Abbott (2020) Abbott Launches Third Covid-19 Test, A Laboratory-Based Antibody Blood Test That Will Ship In The U.S. Starting Tomorrow. 15 Apr 2020. Available at: https://abbott.mediaroom.com/2020-04-15-Abbott-Launches-Third-COVID-19-Test-a-Laboratory-Based-Antibody-Blood-Test-That-Will-Ship-in-the-U-S-Starting-Tomorrow (accessed 17 Apr 2020)
366. Abbott (2020) Abbott Launches COVID-19 Antibody Test. 15 Apr 2020. Available at: https://www.abbott.com/corpnewsroom/product-and-innovation/abbott-launches-covid-19-antibody-test.html (accessed 17 Apr 2020)
367. Abbott Laboratories Inc (2020) SARS-CoV-2 IgG Available at: https://www.fda.gov/media/137383/download
368. FDA (2020) ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY COVID-19 ELISA IGG ANTIBODY TEST (MOUNT SINAI LABORATORY) Available at: https://www.fda.gov/media/137029/download
369. Pellecome (2020) COVID -19 IgM/IgG Rapid Test Cassette (WB/S/P). Available at: https://pellecome.com/wp-content/uploads/2020/03/ClungeneIFU-Amended.pdf (accessed 22 April)
370. BiotesT (2020) Sell Sheet COVID-19 IgG/IgM Rapid Test. Available at: http://en.biotests.com.cn/newsitem/278470281 (accessed 22 April)
371. Lyher (2020) Novel Coronavirus (2019-nCoV)) IgM/IgG Antibody Combo Test Kit (Colloidal Gold). Available at: https://lyherbiotech.com/products/novel-coronavirus-2019-ncov-igm-igg-antibody-combo-test-kit (accessed 22 April)
372. CTK Biotech (2020) New! CTK launches Test kits for COVID-19. Available at: https://ctkbiotech.com/covid-19/ (accessed 22 April)
373. Hightop (2020) SARS-CoV-2 (COVID-19) IgM/IgG Ab Rapid Test. Available at: http://www.hightopqd.com/en/productny.aspx?ProductsID=567&oid=246&CateId=73 (accessed 22 April)
374. BioSite (2020) SARS-CoV-2 Ab Rapid Test: Rapid Test Kit for Detection of Total Antibodies to SARS-CoV-2. Available at: https://www.nordicbiosite.com/product/256-WJ-2750-50/SARSCoV2-Ab-Rapid-Test (accessed 22 April)
375. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Camtech Covid-19 IgM/IgG. Available at: //www.hsa.gov.sg/docs/default-source/hprg-mdb/camtech-diagnostics-pte-ltd.pdf (accessed 22 April)
376. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biolidics-limitedf4a2e74b1cfb4293ab970ab638db5e77.pdf (accessed 22 April)
377. Authority HS (2020) Provisional Authorisation for COVID-19 Tests: VivaDiag™ COVID-19 IgM/IgG Rapid Test Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/everest-links-pte-ltd.pdf (accessed 22 April)
378. Health Sciences Authority (2020) Provisional Authorisation for COVID-19 Tests. Available at: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/grit_provisional-authorisation-for-covid-19-tests_24042020.pdf (accessed 30 April)
379. Diagnostics OC (2020) INSTRUCTIONS FOR USE: CoV2G. Available at: https://www.fda.gov/media/137363/download (accessed 30 April)
380. Molecular D (2020) LIAISON® SARS-CoV-2 S1/S2 IgG ([REF] 311460). Available at: https://www.fda.gov/media/137359/download (accessed 30 April)
381. Bloomberg (2020) Shenzen YHLO Biotech Co,. LTD. Available at: https://www.bloomberg.com/profile/company/1797419D:CH (accessed 7 May)
382. Infantino M et al Diagnostic accuracy of an automated chemiluminescent immunoassay for anti-SARS-CoV-2 IgM and IgG antibodies: an Italian experience. *Journal of Medical Virology*.n/a(n/a). Available at: https://onlinelibrary.wiley.com/doi/abs/10.1002/jmv.25932
383. Healgen (2020) COVID-19 Antibody Rapid Detection Kit. Available at: https://www.healgen.com/if-respiratory-covid-19 (accessed 7 May)
384. FDA (2020) Platelia SARS-CoV-2 Total Ab. Available at: https://www.fda.gov/media/137493/download (accessed 7 May)
385. Wadsworth Center (2020) Departhment of Health, Wadsworth Center. Available at: https://wadsworth.org/ (accessed 7 May)

386. FDA (2020) ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY NEW YORK SARS-COV MICROSPHERE IMMUNOASSAY FOR ANTIBODY DETECTION. Available at: https://www.fda.gov/media/137541/download (accessed 7 May)
387. FDA (2020) Elecsys Anti-SARS-CoV-2. Available at: https://www.fda.gov/media/137605/download (accessed 7 May)
388. Ong SWX et al (2020) Air, Surface Environmental, and Personal Protective Equipment Contamination by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) From a Symptomatic Patient. *JAMA.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32129805
389. Huang C et al (2020) Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet.*395(10223):497-506. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31986264
390. Phan LT et al (2020) Importation and Human-to-Human Transmission of a Novel Coronavirus in Vietnam. *N Engl J Med.*382(9):872-874. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31991079
391. Chen N et al (2020) Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet.*395(10223):507-513. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32007143
392. Holshue ML et al (2020) First Case of 2019 Novel Coronavirus in the United States. *N Engl J Med.*382(10):929-936. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32004427
393. Lei J et al (2020) CT Imaging of the 2019 Novel Coronavirus (2019-nCoV) Pneumonia. *Radiology.*295(1):18. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32003646
394. Liu P et al (2020) 2019 Novel Coronavirus (2019-nCoV) Pneumonia. *Radiology.*295(1):19. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32013795
395. Chang et al (2020) Epidemiologic and Clinical Characteristics of Novel Coronavirus Infections Involving 13 Patients Outside Wuhan, China. *JAMA.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32031568
396. Fang Y et al (2020) CT Manifestations of Two Cases of 2019 Novel Coronavirus (2019-nCoV) Pneumonia. *Radiology.*295(1):208-209. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32031481
397. Liu K et al (2020) Clinical characteristics of novel coronavirus cases in tertiary hospitals in Hubei Province. *Chin Med J (Engl).* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32044814
398. Wang D et al (2020) Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32031570
399. Liu Y et al (2020) Clinical and biochemical indexes from 2019-nCoV infected patients linked to viral loads and lung injury. *Sci China Life Sci.*63(3):364-374. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32048163
400. Wang Z et al (2020) Clinical characteristics and therapeutic procedure for four cases with 2019 novel coronavirus pneumonia receiving combined Chinese and Western medicine treatment. *Biosci Trends.*14(1):64-68. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32037389
401. Bastola A et al (2020) The first 2019 novel coronavirus case in Nepal. *Lancet Infect Dis.*20(3):279-280. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32057299
402. Chen H et al (2020) Clinical characteristics and intrauterine vertical transmission potential of COVID-19 infection in nine pregnant women: a retrospective review of medical records. *Lancet.*395(10226):809-815. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32151335
403. Duan YN et al (2020) Pre- and Posttreatment Chest CT Findings: 2019 Novel Coronavirus (2019-nCoV) Pneumonia. *Radiology.*295(1):21. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32049602
404. Huang P et al (2020) Use of Chest CT in Combination with Negative RT-PCR Assay for the 2019 Novel Coronavirus but High Clinical Suspicion. *Radiology.*295(1):22-23. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32049600
405. Li X et al (2020) COVID-19 Infection Presenting with CT Halo Sign. *Radiology: Cardiothoracic Imaging.*2(1):e200026. Available at:
406. Liu YC et al (2020) A Locally Transmitted Case of SARS-CoV-2 Infection in Taiwan. *N Engl J Med.*382(11):1070-1072. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32050059
407. Liu T et al (2020) Spectrum of Chest CT Findings in a Familial Cluster of COVID-19 Infection. *Radiology: Cardiothoracic Imaging.*2(1):e200025. Available at:

408. Ng M-Y et al (2020) Imaging Profile of the COVID-19 Infection: Radiologic Findings and Literature Review. *Radiology: Cardiothoracic Imaging.*2(1). Available at:
409. Silverstein WK et al (2020) First imported case of 2019 novel coronavirus in Canada, presenting as mild pneumonia. *Lancet.*395(10225):734. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32061312
410. The Novel Coronavirus Pneumonia Emergency Response Epidemiology Team (2020) Vital surveillances: the epidemiological characteristics of an outbreak of 2019 novel coronavirus disease (COVID-19)—China, 2020. China CDC Weekly Updated Available at: http://weekly.chinacdc.cn/en/article/id/e53946e2-c6c4-41e9-9a9b-fea8db1a8f51 (accessed 18 Feb 2020)
411. Wei M et al (2020) Novel Coronavirus Infection in Hospitalized Infants Under 1 Year of Age in China. *JAMA.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32058570
412. Wu Y et al (2020) Longitudinal CT Findings in COVID-19 Pneumonia: Case Presenting Organizing Pneumonia Pattern. *Radiology: Cardiothoracic Imaging.*2(1):e200031. Available at:
413. Van Cuong L et al (2020) The first Vietnamese case of COVID-19 acquired from China. *Lancet Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32085849
414. Xu Z et al (2020) Pathological findings of COVID-19 associated with acute respiratory distress syndrome. *Lancet Respir Med.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32085846
415. Fang Y et al (2020) Sensitivity of Chest CT for COVID-19: Comparison to RT-PCR. *Radiology.*200432. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32073353
416. Huang WH et al (2020) 2019 novel coronavirus disease (COVID-19) in Taiwan: Reports of two cases from Wuhan, China. *J Microbiol Immunol Infect.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32111449
417. Zou L et al (2020) SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. *N Engl J Med.*382(12):1177-1179. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32074444
418. Xu XW et al (2020) Clinical findings in a group of patients infected with the 2019 novel coronavirus (SARS-Cov-2) outside of Wuhan, China: retrospective case series. *BMJ.*368:m606. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32075786
419. Zhu N et al (2020) A Novel Coronavirus from Patients with Pneumonia in China, 2019. *N Engl J Med.*382(8):727-733. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31978945
420. Pan Y et al (2020) Viral load of SARS-CoV-2 in clinical samples. *Lancet Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32105638
421. Wei J et al (2020) 2019 Novel Coronavirus (COVID-19) Pneumonia: Serial Computed Tomography Findings. *Korean J Radiol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32100486
422. Yang W et al (2020) Clinical characteristics and imaging manifestations of the 2019 novel coronavirus disease (COVID-19):A multi-center study in Wenzhou city, Zhejiang, China. *J Infect.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32112884
423. Lan L et al (2020) Positive RT-PCR Test Results in Patients Recovered From COVID-19. *JAMA.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32105304
424. Cai J et al (2020) A Case Series of children with 2019 novel coronavirus infection: clinical and epidemiological features. *Clin Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32112072
425. Guan WJ et al (2020) Clinical Characteristics of Coronavirus Disease 2019 in China. *N Engl J Med.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32109013
426. Kam KQ et al (2020) A Well Infant with Coronavirus Disease 2019 (COVID-19) with High Viral Load. *Clin Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32112082
427. Lillie PJ et al (2020) Novel coronavirus disease (Covid-19): The first two patients in the UK with person to person transmission. *J Infect.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32119884
428. Ling Y et al (2020) Persistence and clearance of viral RNA in 2019 novel coronavirus disease rehabilitation patients. *Chin Med J (Engl).* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32118639
429. Tian S et al (2020) Pulmonary Pathology of Early-Phase 2019 Novel Coronavirus (COVID-19) Pneumonia in Two Patients With Lung Cancer. *J Thorac Oncol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32114094

430. Li K et al (2020) The Clinical and Chest CT Features Associated with Severe and Critical COVID-19 Pneumonia. *Invest Radiol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32118615
431. Wu J et al (2020) Clinical Characteristics of Imported Cases of COVID-19 in Jiangsu Province: A Multicenter Descriptive Study. *Clin Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32109279
432. Xiong Y et al (2020) Clinical and High-Resolution CT Features of the COVID-19 Infection: Comparison of the Initial and Follow-up Changes. *Invest Radiol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32134800
433. Young BE et al (2020) Epidemiologic Features and Clinical Course of Patients Infected With SARS-CoV-2 in Singapore. *JAMA.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32125362
434. Zhu Y et al (2020) Clinical and CT imaging features of 2019 novel coronavirus disease (COVID-19). *J Infect.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32142928
435. Fan BE et al (2020) Hematologic parameters in patients with COVID-19 infection. *Am J Hematol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32129508
436. Hu Z et al (2020) Clinical characteristics of 24 asymptomatic infections with COVID-19 screened among close contacts in Nanjing, China. *Sci China Life Sci.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32146694
437. Li Y et al (2020) Coronavirus Disease 2019 (COVID-19): Role of Chest CT in Diagnosis and Management. *AJR Am J Roentgenol.*1-7. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32130038
438. Yan G et al (2020) Covert COVID-19 and false-positive dengue serology in Singapore. *Lancet Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32145189
439. Liu Y et al (2020) Clinical manifestations and outcome of SARS-CoV-2 infection during pregnancy. *J Infect.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32145216
440. Wang L et al (2020) The clinical dynamics of 18 cases of COVID-19 outside of Wuhan, China. *Eur Respir J.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32139464
441. Xia W et al (2020) Clinical and CT features in pediatric patients with COVID-19 infection: Different points from adults. *Pediatr Pulmonol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32134205
442. Zhou S et al (2020) CT Features of Coronavirus Disease 2019 (COVID-19) Pneumonia in 62 Patients in Wuhan, China. *AJR Am J Roentgenol.*1-8. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32134681